UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, *et al., ex rel.* [UNDER SEAL],	§	
Plaintiffs,	§	Civil Action No.
v.	§	
[UNDER SEAL],	§	
Defendant.	§	**Filed Under Seal Pursuant to 31 U.S.C. § 3730**

SECOND AMENDED COMPLAINT OF THE UNITED STATES

FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, WASHINGTON, the Commonwealth of MASSACHUSETTS, VIRGINIA, and the DISTRICT OF COLUMBIA, *ex rel.*, TOBY TRAVIS, Plaintiffs, v. GILEAD SCIENCES, INC., BIOPLUS PHARMACY, INC, GOOD HEALTH, INC. D/B/A PREMIER PHARMACY SERVICES, WALGREENS, COVANCE, HEALTHSTAR CES, ECHOSENS NORTH AMERICA and UNKNOWN SPECIALTY PHARMACIES 1-100, Defendants.	§	Civil Action No. 17-1183 **Filed Under Seal Pursuant to 31 U.S.C. § 3730**

SECOND AMENDED COMPLAINT

FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730

The United States of America (the "United States") and the Plaintiff States (defined below) (the United States and Plaintiff States are collectively referred to herein as the "Government"), by and through their *qui tam* Relator, Toby Travis ("Relator"), bring this action under the Federal False Claims Act, 31 U.S.C. § 3729 *et seq*. (the "False Claims Act" or "FCA") and the false claims acts of the respective Plaintiff States against Gilead Sciences ("Gilead," "Company" or "Defendant"), Healthstar CES, Covance, Bioplus Pharmacy, Inc. ("Bioplus"), Good Health, Inc., d/b/a Premier Pharmacy Services ("Premier"), Walgreens, Echosens North America ("Echosens NA" or "Echosense") and 100 unknown specialty pharmacies (Gilead, Bioplus, Premier, Walgreens, Healthstar, Echosens NA and the unknown specialty pharmacies shall be referred herein as "Defendants"), to recover all damages, penalties, and other remedies provided by the False Claims Act, and analogous state statutes,[1] and for their complaint ("Complaint") allege:

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[1] Specific citations for relevant state *qui tam* statutes are as follows: California False Claims Act, Cal. Gov't Code § 12650 *et seq.*; Colorado Medicaid False Claims Act, C.R.S.A. § 25.5-4-304 *et seq.*; Connecticut False Claims Act, Conn. Gen. Stat. § 17b-301a *et seq.*; Delaware False Claims and Reporting Act, 6 Del. C. Ann. tit. 6 § 1201 *et seq.*; Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*; Georgia False Medicaid Claims Act, Ga. Code Ann., § 49-4-168 *et seq.*; Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*; Illinois False Claims Act, 740 ILCS 175/1 *et seq.*; Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5 *et seq.*; Iowa False Claims Law, I.C.A. § 685.1 *et seq.*; Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 437.1 *et seq.*; Maryland False Claims Act, Md. Code Ann. Health - Gen., § 2-601 *et seq.;* Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.601 *et seq.*; Minnesota False Claims Act, M.S.A. § 15C.01 *et seq.*; Montana False Claims Act, MCA § 17-8-401 *et seq.*; Nevada False Claims Act, Nev. Rev. Stat. Ann. § 357.010 *et seq.*; New Jersey False Claims Act, N.J.S.A. § 2A:32C-1 *et seq.*; New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.*; New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. § 44-9-1 *et seq.*; New York State False Claims Act, N.Y. State Fin. Law § 188 *et seq.*; North Carolina False Claims Act, N.C. Gen. Stat. Ann. § 1-605 *et seq.*; Oklahoma Medicaid False Claims Act, 63 Okl. Stat. Ann. Tit. 63, § 5053 *et seq.*; Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.*; Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*; Texas False Claims Act, V.T.C.A. Hum. Res. Code § 36.001 *et seq.*; Vermont False Claims Act, Vt. Stat. Ann. tit. 32, § 630 *et seq.*; Washington Medicaid Fraud Act, Wash. Rev. Code Ann. § 74.66.005 *et seq.*; Massachusetts False Claims Act, Mass. Gen. Laws Ann. Ch. 12 § 5(A) *et seq.*; Virginia Fraud Against Tax Payers Act, Va. Code Ann. § 8.01-216.1 *et seq.*; and District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. § 2-308.13 *et seq.*

1. Based on the Relator's personal knowledge and further investigation, sufficient evidence exists to allege that Defendants have violated and continue to violate the False Claims Act, 31 U.S.C. § 3729, and the false claims acts of the Plaintiff States, by submitting fraudulent bills to the government (and/or through its conduct in causing others to submit fraudulent bills to the government) as a result of kickbacks, off-label marketing, and other prohibited marketing strategies.

2. The illegal acts alleged herein began in at least July 2013 and continue through the present ("Covered Period").

PARTIES

3. Relator was hired by Gilead as a Hepatic Therapeutic Specialist on July 1, 2013. In this role, from July 2013 until October 2014, Relator promoted Sovaldi in southern Oregon and the greater metropolitan area of Redding, California. Relator's employment with Gilead ended in mid-to-late October 2014. Immediately after leaving Gilead, Relator was hired as a 1099 sales representative by Premier, assigned to the California, Oregon, and Alaska territories.

4. While employed at Gilead, Relator reported directly to Northwest Regional Manager, Brad Peacock, responsible for the Washington, Oregon, Idaho, Utah, Montana, Alaska, Northern California, Northern Nebraska, and Nevada sales regions. Relator also reported to Western Region Senior Sales Director, Oriana Wiklund.

5. Prior to his employment with Gilead, Relator worked in the pharmaceutical industry for over twelve years, including three years at TAP Pharmaceuticals where he served in the role of Senior Gastrointestinal Specialist and six years at Genentech where he served as a Virology and Hepatology Specialist. Relator attended Northwest Christian University from 1998 to 2002 and received a Bachelor of Arts in Business Administration and Management degree.

From 2009 to 2011, Relator attended Gonzaga University and received a Master's degree in Business Administration and Management.

6. Plaintiff United States, acting through the Department of Health and Human Services ("HHS"), and its Centers for Medicare and Medicaid Services ("CMS"), administers the Health Insurance Program for the Aged and Disabled, established by Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.* ("Medicare").

7. The Plaintiff States are the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Washington, the Commonwealths of Massachusetts and Virginia, and the District of Columbia. They each bring claims for Defendants' violations of their respective state false claims acts, as set forth in detail in the Counts, below.

8. Gilead is a biopharmaceutical company headquartered in Foster City, California. Gilead owns the drugs Sovaldi and Harvoni.

9. Relator and the Government also bring claims against the specialty pharmacies which, as discussed below, were providing Gilead remuneration in exchange for Sovaldi and Harvoni prescription referrals.

10. Bioplus is, according to its website, "one of the largest and most respected specialty pharmacies" and is based out of Altamonte Springs, Florida.

11. Premier is a specialty pharmacy, licensed in all 50 states, which employs approximately 300 people working out of two pharmacy dispensing and distribution centers. In addition, and as discussed in more detail below, Premier was also paying sales representatives from Gilead and other pharmaceutical companies in exchange for prescriptions and providing free

FibroScan Clinics to providers, in violation of the Anti-Kickback Statute ("AKS").

12. Walgreens is the second largest pharmacy chain in the United States, and operates as a typical retail pharmacy as well as a specialty pharmacy.

13. Unknown Specialty Pharmacies 1-100 represent other pharmacies that entered into similar arrangements with Gilead in violation of the federal AKS, but which their identities are currently unknown.

14. Covance provides a variety of services to pharmaceutical manufacturers.

15. Healthstar CES provides clinical educators to pharmaceutical manufacturers. As discussed in more detail below, Gilead used Healthstar's nurse educators to unlawfully induce physicians to prescribe Sovaldi and Harvoni.

16. Echosens NA is a subsidiary of Echosens Group, the world's number one provider of non-invasive point of care medical devices dedicated to assessment of chronic liver diseases. According to its website, Echosens NA was established in 2015 to provide the United States market with direct support for the FibroScan product line.

JURISDICTION AND VENUE

17. Jurisdiction in this Court is proper pursuant to 31 U.S.C. §§ 3732(a) and 3730(b). This Court also has jurisdiction pursuant to 28 U.S.C. § 1331.

18. The Court may exercise personal jurisdiction over the Defendants, and venue is proper in this Court pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391 because the acts proscribed by 31 U.S.C. § 3729 *et seq.*, and complained of herein took place in part in this District and the Defendants transacted business in this District as described herein.

19. Pursuant to 31 U.S.C. § 3730(b)(2), Relator prepared and will serve the Complaint on the Attorney General of the United States, and the United States Attorney for the Eastern

District of Pennsylvania, as well as a statement of all material evidence and information currently in its possession and of which it is the original source. The disclosure statement is supported by material evidence known to the Relator at the time of filing establishing the existence of Defendants' false claims. Because the statements include attorney-client communications and work product of Relator' attorneys, and will be submitted to those Federal officials in their capacity as potential co-counsel in the litigation, Relator understand these disclosures to be confidential and exempt from disclosure under the Freedom of Information Act. 5 U.S.C. § 552; 31 U.S.C. § 3729(c).

BACKGROUND

The False Claims Act

20. The False Claims Act provides, in pertinent part:

(a) Liability for Certain Acts.—

(1) In general.— Subject to paragraph (2), any person who—

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);
>
> (D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;
>
> (E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104–410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

(3) Costs of civil actions.— A person violating this subsection shall also be liable to the United States Government for the costs of a civil action brought to recover any such penalty or damages.

(b) Definitions.— For purposes of this section—

(1) the terms "knowing" and "knowingly"—

(A) mean that a person, with respect to information—

(i) has actual knowledge of the information;

(ii) acts in deliberate ignorance of the truth or falsity of the information; or

(iii) acts in reckless disregard of the truth or falsity of the information; and

(B) require no proof of specific intent to defraud;

(2) the term "claim"—

(A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—

(i) is presented to an officer, employee, or agent of the United States; or

(ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the

> Government's behalf or to advance a Government program or interest, and if the United States Government—
>
> > (I) provides or has provided any portion of the money or property requested or demanded; or
> >
> > (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and
>
> (B) does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual's use of the money or property;
>
> (3) the term "obligation" means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment; and
>
> (4) the term "material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

21. Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Public Law 114-74, Sec. 701, False Claims Act civil penalties were increased to a minimum of $10,781, and a maximum of $21,563, for violations occurring on or after November 2, 2015. *See also* 28 C.F.R. § 85.5.

SUBSTANTIVE ALLEGATIONS

I. Overview of Medicare and Its Benefits

22. Medicare is a federal health insurance system for people 65 and older and for people under 65 with certain disabilities.

23. Medicare Part D began January 1, 2006 and pays for prescription drug benefits for the elderly and disabled. 42 U.S.C. § 1395w-101 *et seq*. All persons enrolled in Medicare Part A and/or Medicare Part B are eligible to enroll in a prescription drug plan under Part D. HHS, through its component agency, CMS, contracts with private companies (or "sponsors") authorized to sell

Part D insurance coverage. Such companies are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts.

24. Medicare Part D requires all participants in the program – prescription drug plan ("PDP") sponsors, Pharmacy Benefit Managers ("PBM"), and pharmacies – to adhere to all federal laws and regulations, including those designed to prevent fraud, waste, and abuse. 42 C.F.R. § 423.505(h)(1). Under CMS regulations, PDP sponsors' subcontracts with PBMs and pharmacies must contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. § 423.505(i)(3)(v).

25. The federal government's target is to pay 74.5% of the actual costs of basic prescription drug coverage (as defined at 42 U.S.C. § 1395w-1029(a)(3)). 42 U.S.C. § 1395w-115(a). Rather than a straight reimbursement, however, the government uses economic incentives and disincentives to encourage both beneficiaries and Part D Plan sponsors to reduce costs. 42 U.S.C. § 1395w-115.

26. For beneficiaries, the disincentives for running-up high drug expenditures include requiring them to pay certain amounts out-of-pocket (in the aggregate referred to as a beneficiary's True Out-Of-Pocket ("TrOOP")). Those sums include:

a) a beneficiary premium equal to 25.5% of the national weighted average plan bid, as adjusted (approximately $350), 42 U.S.C. § 1395w-113(a);

b) a deductible defined as 100% of the first $250, as adjusted (although 90% of Part D Plans eliminate the deductible and use a tiered co-pay), 42 U.S.C. § 1395w-102(b)(1);

c) thereafter a 25% copay on all costs up to the coverage gap, 42 U.S.C. § 1395w-102(b)(2);

d) 100% of costs between $2,250 and $3,600, as adjusted, 42 U.S.C. § 1395w-102(b)(3) & (4) (the "coverage gap" or "donut hole"); and

e) whereafter, the beneficiary enters the catastrophic coverage phase and only pays

a copay of 5%, or $2 for a generic drug and $5 for any other drug. 42 U.S.C. § 1395w-102(b)(4)(A)(i).

27. Because beneficiaries are required to pay a significant copay, and 100% of the cost of drugs while they are in the deductible and coverage gap phases of the program, Medicare Part D provides certain protections to beneficiaries. For example, sponsors must make the negotiated prices available to beneficiaries regardless of what "phase" of the Part D benefit an enrollee is in (*i.e.* deductible, ordinary coverage, coverage gap or catastrophic coverage). In addition, that negotiated price must also remain uniform within a particular pharmacy regardless of what phase of the program the beneficiary is in. Prescription Drug Benefit Manual, Ch. 5 "Benefits and Beneficiary Protections," § 20.6 ("the negotiated price for a particular covered Part D drug purchased at a particular pharmacy must always be the same regardless of what phase of the Part D benefit an enrollee is in").

28. Another beneficiary protection is that, while they are in the deductible or coverage gap phases where they pay 100% of the costs, beneficiaries may avail themselves of a cash price that is better than their PDP's negotiated price if the pharmacy is offering a "'special' price or other discount for all customers, or if the beneficiary is using a discount card." Prescription Drug Benefit Manual, Ch. 14 "Coordination of Benefits," at 50.4.2. If the beneficiary makes such a purchase outside of their plan, their expenditure will still count toward their TrOOP if they report it to their plan. *Id.*

29. For Part D plan sponsors, the program is a quasi-free market model that uses a variety of incentives which are part of the structure of the program. The starting point is that the program only pays the sponsor "interim payments . . . based on the Secretary's best estimate of amounts that will be payable after obtaining all of the information." 42 U.S.C. § 1395w-115(d)(1). In other words, Medicare Part D is not a capitated federal insurance program, but rather an actual

cost program. *Id.*; *see* 42 U.S.C. § 1395w-112(g) (prohibiting states from imposing premium taxes on Part D subsidy since, unlike Part C, the payments are not capitated premiums); *compare to* 42 U.S.C. § 1395w-114(c)(2) (expressly authorizing capitated payment only for those Part D beneficiaries in the lowest income tier who qualify for greater subsidy).

30. In simplest terms, the sponsor submits a bid based on actuarial data estimating the actual cost of providing prescription drugs to its pool of beneficiaries. The government then makes "interim payments" to the sponsor on a monthly basis. As an express condition of receiving those interim payments, the sponsor is required to submit to the government truthful and complete data, including actual cost, for every prescription filled. At the end of each year the government then compares its interim payments to the actual cost data, and determines whether the sponsor owes a refund to the government, or whether the government is required to pay more money in order to meet its subsidy target. In order to further incentivize the sponsor to keep costs down, however, the refund or additional payment is first subject to risk corridors which penalize the sponsor if actual costs exceed its bid, and reward the sponsor if actual costs are below its bid. 42 U.S.C. § 1395w-115(e). As a practical matter, these risk corridors would only slightly increase or decrease the total percentage paid by the government for each prescription.

II. Overview of Medicaid and Its Benefits

31. Medicaid is a joint federal-state program created in 1965 that provides health care benefits for certain groups, primarily the poor and disabled. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on the state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). Among the states, the FMAP is at least 50 percent and is as high as 83 percent.

32. The Medicaid program pays for services pursuant to plans developed by the states

and approved by the HHS Secretary through CMS. 42 U.S.C. § 1396a(a)-(b). States pay doctors, hospitals, pharmacies, and other providers and suppliers of medical items and services according to established rates. 42 U.S.C. §§ 1396b(a)(1), 1903(a)(1). The federal government then pays each state a statutorily-established share of "the total amount expended . . . as medical assistance under the State plan . . . ." *See* 42. U.S.C. § 1396b(a)(1). This federal-to-state payment is known as federal financial participation ("FFP").

33. The Medicaid programs of all states reimburse for prescription drugs. The vast majority of states award contracts to private companies to evaluate and process claims for payment on behalf of Medicaid recipients. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid programs. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, and determines the amount of federal funding each state will be permitted to draw down as it incurs expenditures during the quarter. The state then draws down federal funding as actual provider claims, including claims from pharmacies seeking payment for drugs, are presented for payment. After the end of each quarter, the state then submits to CMS a final expenditure report, which provides the basis for adjustment to the quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures). 42 C.F.R.§ 430.30.

III. The TRICARE Program

34. TRICARE, formerly known as CHAMPUS, is a managed health care program established by the Department of Defense. 10 U.S.C. §§ 1071-1110. TRICARE provides health care benefits to eligible beneficiaries, which include, among others, active duty service members, retired service members, and their dependents.

35. The regulatory authority establishing the TRICARE program does not cover drugs not approved by the FDA. *See* 32 C.F.R. § 199.4(g)(15)(i)(A). TRICARE does not cover drugs used for off-label indications unless such off-label use is proven medically necessary and safe and effective by medical literature, national organizations, or technology assessment bodies. *See* 32 C.F.R. § 199.4(g)(15)(i)(A)(Note).

IV. The United States Food, Drug, and Cosmetic Act

36. The FDA regulates the manufacture, sale, and distribution of drugs and devices in the United States under the authority of the United States Food, Drug and Cosmetic Act ("FDCA"). The FDCA establishes the framework for regulation of, *inter alia*, the sales and marketing activities of pharmaceutical manufacturers in the United States. This authority includes oversight of promotional labeling and advertising for prescription drugs and restricted devices. 21 U.S.C. § 502.

37. The FDCA defines "label" to mean "a display of written, printed, or graphic matter upon the immediate container of any article . . . ." 21 U.S.C. § 321(k). "Labeling" means "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). For a prescription drug or device to comply with the FDCA's requirement of adequate directions for use, its labeling must contain, among other things, information addressing product hazards and other risk information, as specified in FDA regulations. 21 C.F.R. §§ 201.100(d)(1) & (3) and 801.109(d).

38. The FDCA also subjects advertising for prescription drugs and restricted devices to the disclosure of risk and other informational requirements. Advertisements for prescription drugs must include, among other things, "information in brief summary relating to side effects, contraindications, and effectiveness," as specified in FDA regulations. 21 U.S.C. § 352(n).

Advertisements for restricted devices must include "a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications . . . ." 21 U.S.C. § 352(r). Both prescription drug and restricted device advertisements also must not be false or misleading. 21 U.S.C. § 352(q)(1) & 321(n); 21 C.F.R. § 202.1(e)(5).

39. Disease awareness communications are communications disseminated to consumers or health care practitioners that discuss a particular disease or health condition, but do not mention any specific drug or device or make any representation or suggestion concerning a particular drug or device. FDA Guidance for Industry (draft guidance), *"Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms* (January 2004).[2] Help-seeking communications are disease awareness communications directed at consumers. *Id.*

40. Help seeking and disease awareness communications constitutes neither labeling nor advertising. *Id.* Therefore, help seeking and disease awareness communications are not subject to the disclosure of risk information and other requirements for labeling and advertisement communications under the FDCA. *Id.*

41. The FDA will treat as a disease awareness communications any communications by or on behalf of a manufacturer, distributor, or retailer of a drug or device that:

i. discuss a disease or health condition;

ii. if consumer-directed, advise the audience to "see your doctor" for possible diagnosis and/or treatment;

iii. if aimed at health care practitioners, encourage awareness of signs of the particular disease or health condition, or otherwise provide information to assist in the diagnosis of the particular disease or health condition;

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[2] On May 6, 2015, the FDA announced that it was withdrawing the draft guidance. *See* 80 Fed. Reg. 26059. Thus, pharmaceutical manufacturers can now rely on two previously released industry policy guidance releases: Clarification of Policy on Institutional, Corporate, or Health Message Advertising (September 1985) and Institutional/Disease-oriented Advertisements (June 3, 1988).

iv. do not mention a particular drug or device; and

v. do not include any representation or suggestion relating to a particular drug or device.

Id.

42. When a disease awareness communication is presented in a combination with a product promotion communication, in a way that causes the audience to perceive the two pieces as an advertisement or promotional labeling piece, a disease awareness communication may be treated by the FDA as labeling or advertising. *Id.* For example, a purported disease awareness communication disseminated by or on behalf of a drug manufacturer can be subject to the FDA's labeling or advertising requirements if it mentions a specific drug or contains a representation or suggestion concerning a specific drug or device. *Id.*

43. In determining whether a disease awareness communication and promotional communication were disseminated in such a way as to trigger the FDA's advertising or labeling requirements, the FDA focuses on how the audience is likely to perceive the communication. Specifically, the FDA has stated that:

> a supposed disease awareness communication could be properly treated as advertising or promotional labeling if presented in combination with a product claim advertisement or promotional labeling piece in a manner that causes the pieces' messages to be linked together by the audience. In such a case, the combined communication would also communicate a particular product's indication and efficacy for a certain medical condition. If the combined communication does not comply with the act and FDA's advertising or labeling regulations, the communication would cause the promoted product to be misbranded.

Id. See also Enforcement Letter From FDA's Division of Drug Marketing, Advertising, and Communications to Schering Corp. (Aug. 18, 2000) (finding that two advertisements, a help seeking advertisement and a reminder advertisement, which immediately followed each other in a magazine, converted the entire presentation into one full product advertisement, subject to the

FDA's regulations); *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM166052.pdf; FDA Guidance for Industry, *Distributing Scientific and Medical Publications on Unapproved New Uses – Recommended Practices* (February 2014) (stating that scientific or medical journal articles and reference texts and clinical practice guidelines ("CPG") provided by pharmaceutical manufacturers to health care professionals should be distributed "separately from the delivery of information that is promotional in nature. For example, if a sales representative delivers a CPG to a physician in his or her office, the CPG should not be attached to any promotional material the sales representative uses or delivers during the office visit. To the extent that the recipients of the CPG have questions, the sales representative should refer the questions to a medical/scientific officer or department, *and the officer or department to which the referral is made should be independent of the sales and/or marketing departments*.") (emphasis added).

44. Moreover, the FDA has identified two factors which it examines when determining whether two communications together qualify as promotional labeling or advertising. The two factors are: (1) Are the pieces perceptually distinct in use of graphic, visual, thematic, or other presentation elements; and (2) Are the pieces presented in close physical or temporal proximity? *Id.*

45. Of these two factors, the FDA considers the determinant factor to be whether the pieces are perceptually distinct. In addressing this factor, the FDA recommended that manufacturers:

> ensure that their disease awareness communications and reminder promotional pieces or product claim promotional pieces are sufficiently distinctive in terms of their thematic, graphic, visual and other presentation elements so that they will not be perceived as a single promotional piece that includes both a product name and a

use, and is thus subject to the requirements for "labeling" or "advertising" mandated by the act and regulations.

"Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms (January 2004).

V. Anti-Kickback Statute

46. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2)(A) and (B), prohibits offering to pay or paying any remuneration (including any kickback, bribe, or rebate) to any person to induce such person "to purchase . . . any good . . . service, or item for which payment may be made in whole or in part under a Federal healthcare program" or "to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program." *Id.* Pursuant to the Anti-Kickback Statute, it is unlawful to knowingly offer or pay any remuneration in cash or in kind in exchange for the referral of any product (including a prescription drug product) for which payment is sought from any federally-funded health care program, including Medicare and Medicaid. In order to ensure compliance, every federally-funded health care program requires every provider or supplier to ensure compliance with the provisions of the Anti-Kickback Statute and other federal laws governing the provision of health care services in the United States.

47. For purposes of the AKS, "remuneration" includes the transfer of anything of value, in cash or in-kind, directly or indirectly, covertly or overtly. Importantly, the statute has been interpreted to cover *any arrangement where one purpose of the remuneration is to obtain money for referral of services or to induce further referrals. United States v. Kats*, 871 F. 2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F. 2d 68 (3rd Cir. 1985), *cert. denied*, 476 U.S. 988 (1985).

48. A violation of the Anti-Kickback Statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Any party convicted under the

Anti-Kickback Statute must be excluded from federal health care programs for a term of at least five years. 42 U.S.C. § 1320a-7(b).

49. Compliance with the Anti-Kickback Statute is required for reimbursement of claims from federal health care programs, and claims made in violation of the law are actionable civilly under the FCA. 42 U.S.C. § 1320a-7b(g) (2010) (stating, in part, that a "claim that includes items or services resulting from a violation of . . . [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the FCA]. . . ."); *see also United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 315 (3d Cir. 2011) (stating "[c]ompliance with the AKS is clearly a condition of payment under Parts C and D of Medicare" and holding that "appellants, by alleging that appellees violated the AKS while submitting claims for payment to a federal health insurance program, have stated a plausible claim for relief under the FCA.").

50. The Anti-Kickback Statute was amended in March 2010 as part of the Patient Protection and Affordable Care Act ("PPACA"), which clarified that all claims resulting from a violation of the Anti-Kickback Statute are also a violation of the FCA. 42 U.S.C. § 1320a-7(b)(g). The PPACA also amended the Social Security Act's "intent requirement" to make clear that violations of its anti-kickback provisions, like violations of the FCA, may occur even if an individual does "not have actual knowledge" or "specific intent to commit a violation." Public Law No. 111-148, § 6402(h).

VI. The Illinois Insurance Fraud Prevention Act

51. While the federal and state FCA statutes protect *public* insurance entities from fraud, Illinois is unique in permitting whistleblowers to bring a *qui tam* action against any person or company that defrauds private insurance companies and share in the recovery. *See* ICFPA, 740 I.L.C.S §§ 92/1, *et seq.*

52. Rather than bringing the case on behalf of the government and fellow taxpayers, a ICFPA relator brings the case on behalf of the government *and* the relevant private insurance companies' policyholders.

VII. Overview of Coverage and Reimbursement Process

53. Reimbursement Support Services ("RSS") include a provider's administrative tasks associated with prescribing a patient medication, such as coverage determinations, benefit verifications, prior authorizations, and coverage appeals. Physician practices spend a significant amount of time handling these administrative responsibilities associated with prescribing patients medication. For example, according to a 2009 study, in 2006, each week the average physician practice devoted 1 hour of physician time, 13.1 hours of nursing time, and 6.3 hours of clerical time to performing prior authorizations alone. *See* "What Does It Cost Physician Practices To Interact With Health Insurance Plans," Lawrence P. Casalino, et al, *Health Affairs* 28.4 (2009): w5330w543 at w537.

54. Under Medicare, a coverage determination is a process wherein a provider contacts the carrier and verifies the nature and extent of a patient's drug benefit coverage. A Medicare coverage determination is particularly cumbersome and time consuming given the complexity of many Part D plans that have four coverage phases.

55. A "prior authorization" requires that a provider first obtain prior approval from the patient's health insurance plan before prescribing certain medications. Part D carriers use the prior authorization process as a means to contain costs associated with expensive medications, like Sovaldi and Harvoni. That is, if a provider wants to prescribe an expensive drug like Sovaldi or Harvoni, the Part D carrier will require that the provider "make the case" for prescribing the drug over a cheaper drug.

56. The prior authorization process is particularly cumbersome and is widely reviled by office providers' staff because of the paperwork, time, and resources that must be expended to obtain a prior authorization for an individual patient. Further, even if a provider obtains a patient's Part D prior authorization, that prior authorization may only be valid for a limited time, such as for one year, and sometimes for only one month. After that, the provider's staff must start the prior authorization process over again.

57. Coverage appeals occur when an insurance carrier denies coverage or prior authorization for a particular drug and the beneficiary challenges the carrier's coverage decision. Importantly, the tasks necessary to complete a prior authorization and/or coverage appeal always require that the provider give direct input regarding the patient's medical history, clinical and/or laboratory findings, and other information to establish the patient's medical necessity for a drug. Further, the provider and/or provider's staff must also develop specialized knowledge about each drug plan's unique prior authorization and/or coverage appeal criteria.

58. Benefit verifications are when a provider's staff determines the amount of his/her patient's prescription drug coverage. Benefit verifications are conducted daily by office based staff as part of the administrative responsibilities associated with patient care. Performing benefit verifications are complicated and time consuming.

59. Under Medicare, the prescribing physician's office staff is responsible for performing these administrative functions associated with RSS on behalf of their patients. As a result, and has been documented in numerous publications, these administrative duties require a provider to devote a significant amount of their office staff's time and resources to complete.

60. Ensuring that insurance providers covered prescriptions for Sovaldi and Harvoni was a top priority of Gilead. Given the extremely high cost of these drugs, insurance providers,

including government healthcare programs, have strict and complex coverage requirements for these drugs. As a result, the RSS associated with prescribing Sovaldi and Harvoni are significantly more complicated than the RSS associated with other, less expensive drugs. The complex nature of the RSS insurance providers require for Sovaldi and Harvoni in some cases resulted in providers deciding to prescribe a different drug with less complicated RSS requirements. To address this issue, and others, Gilead created its Support Path program.

61. According to Relator, after a physician decided to prescribe his/her patient to Sovaldi or Harvoni, they would submit a form, which also indicated the provider's preferred specialty pharmacy.

VIII. Defendants' Fraudulent Conduct

A. Introduction to Gilead's Hepatitis C Virus Drugs Sovaldi and Harvoni

62. Sovaldi (sofosbuvir) is a nucleotide analogue inhibitor, which acts as an imposter to trick the hepatitis C virus ("HCV"). Sovaldi blocks a polymerase enzyme that plays an essential role in HCV replication. Sovaldi was approved by the FDA on December 6, 2013. Sovaldi's FDA approved label states that:

> SOVALDI is a hepatitis-C virus (HCV) nucleotide analog NS5B polymerase inhibitor indicated for the treatment of genotype 1, 2, 3 or 4 chronic hepatitis C virus (HCV) infection as a component of a combination antiviral treatment regimen.

63. Further, Sovaldi's FDA approved label states that Sovaldi should be administered as follows:

- One 400 mg tablet taken once daily with or without food. (2.1)
- Should be used in combination with pegylated interferon and ribavirin or in combination with ribavirin for the treatment of HCV. Recommended combination therapy: (2.1)

Patient Population	Treatment	Duration

Genotype 1 or 4	SOVALDI + peg-interferon alfa + ribavirin	12 weeks
Genotype 2	SOVALDI + ribavirin	12 weeks
Genotype 3	SOVALDI + ribavirin	24 weeks

- HCV/HIV-1 co-infection: For patients with HCV/HIV-1 co-infection, follow the dosage recommendations in the table above. (2.1)
- SOVALDI in combination with ribavirin for 24 weeks can be considered for patients with genotype 1 infection who are interferon ineligible. (2.1)
- Should be used in combination with ribavirin for treatment of HCV in patients with hepatocellular carcinoma awaiting liver transplantation for up to 48 weeks or until liver transplantation, whichever occurs first. (2.1)
- A dosage recommendation cannot be made for patients with severe renal impairment or end stage renal disease.

64. According to its FDA approved label, Harvoni is a fixed-dose combination of ledipasvir, a hepatitis-C virus NS5A inhibitor, and sofosbuvir (Sovaldi), and is indicated with or without ribavirin for the treatment of chronic hepatitis C virus genotype 1, 4, 5 or 6 infection.

65. Harvoni's FDA approved label states that the drug should be administered as follows:

- Recommended dosage: One tablet (90 mg of ledipasvir and400 mg of sofosbuvir) taken orally once daily with or without food (2.1)
- Recommended treatment regimen and duration: (2.1)

	Patient Population	**Regimen and Duration**
Genotype 1	Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	HARVONI 12 weeks
	Treatment-experienced without cirrhosis	HARVONI 12 weeks
	Treatment-experienced with compensated cirrhosis (Child-Pugh A)	HARVONI 24 weeks
	Treatment-naïve and treatment experienced with	HARVONI + ribavirin 12 weeks

	decompensated cirrhosis (Child-Pugh B or C)	
Genotype 1 or 4	Treatment-naïve and treatment experienced liver transplant recipients without cirrhosis, or with compensated cirrhosis (Child-Pugh A)	HARVONI + ribavirin 12 weeks
Genotype 4, 5, or 6	Treatment-naïve and treatment experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	HARVONI 12 weeks

- HCV/HIV-1 co-infection: For patients with HCV/HIV-1 co-infection, follow the dosage recommendations in the table above (2.1)
- If used in combination with ribavirin, follow the recommendations for ribavirin dosing and dosage modifications
- A dosage recommendation cannot be made for patients with severe renal impairment or end stage renal disease.

B. False Claims Act Violations

66. As discussed in more detail below, Gilead has engaged in a host of misconduct in relation to its promotion of its drugs Sovaldi and Harvoni. These prohibited marketing practices have resulted in claims submitted to government healthcare programs tainted by a violation of the AKS and other rules and regulations, and as a result have violated the FCA.

67. To provide some background information, Relator was hired as a Sovaldi sales representative in July 2013, approximately six months prior to the FDA's approval of Sovaldi. At the time Relator was hired, sales representatives were purportedly intended to promote the hepatitis C disease state and target high prescribers of hepatitis-C medications so prescriptions could be secured the first day the drug was approved.

68. Upon being hired, sales representatives were required to perform two weeks of at home training, called Core Training, which occurred in the beginning of July 2013. Following

Core Training, sales representatives were to attend a two-week training in Foster City, CA, called the On-Boarding Meeting from July 22, 2013 to August 2, 2013.

69. The first week of the On-Boarding Meeting in Foster City focused on administrative details, and where Gilead's Human Resources department strongly encouraged the sales representatives to participate in the Employee Stock Purchase Plan ("ESPP"), rather than the 401k. The second week of the On-Boarding Meeting focused on providing extensive clinical training on the current HCV landscape and the new Sofosbuvir molecule. During this portion of the training, Gilead's Director of Marketing (and current COO) Kevin Young told the sales force "you are the CEO of your own territory, you have complete autonomy and we are giving you the green light to do whatever it takes to drive sales."

70. Following the On-Boarding Meeting, in August 2013, Relator's district sales team was flown to San Diego for a two to three day preceptorship with regional thought leader, Dr. Paul Pockros at Scripps Clinic, a leading fellowship-trained gastroenterologist and hepatologist whose expertise is the treatment of Hepatitis C and end-stage liver disease. Several teams in the Western Region completed preceptorships with Dr. Pockros. In fact, from August to December 2013, Gilead paid Dr. Pockros $43,995.08 for services including these preceptorships. Other sales district teams were flown to preceptorships with regional Key Opinion Leaders in their regions.

71. Gilead held the Sovaldi Launch Meeting from November 11 to November 15, 2013 in Phoenix, AZ in anticipation of Sovaldi's approval on December 6, 2013. Approximately ten months later, Gilead held the Harvoni Launch Meeting from September 15 to September 19, 2014 at the Lowes Hotel in Hollywood, CA in anticipation of Harvoni's approval on October 10, 2014. Sales training for the Harvoni launch consisted of a two-week pre-launch home-study, followed by brand awareness training conducted at the launch meeting.

72. One of the major concerns for Gilead was pushback from providers due to the extremely high cost of Sovaldi and Harvoni. Indeed, the entire sales force was instructed by Gilead not to speak with the media if contacted. According to Relator, at the time Sovaldi was launched, both sales representatives and Gilead physician speakers were doing damage control due to the outrage from the medical community over the drugs' high cost. Gilead instructed sales representatives and physician speakers to push the message that treating patients with Sovaldi, and later Harvoni, was actually a cost saving treatment option because these drugs have high sustained virologic response ("SVR") rates, which they promoted as a "cure," and therefore kill the disease.

73. SVR is the ability to sustain an undetectable viral load for 12 weeks (SVR-12) and 24 weeks (SVR-24) following completion of therapy. Following hepatitis C therapy, the blood is tested to measure viral activity with the ultimate goal of achieving an undetectable viral load. An undetectable result does not mean zero or the complete absence of viral activity in the body; rather it is defined as having no *detectable* virus in your blood using current testing technologies. SVR-24 is considered a "cure," while patients with SVR-12 are usually able to achieve SVR-24. Most patients that achieve an SVR-24 are unlikely to experience viral rebound (i.e., a return of virus).

74. According to Relator, the pitch focused on the "cost per SVR" to demonstrate the cost savings of Sovaldi. As a result, according to Gilead, money is saved because there is no need to continually treat the patient's condition. For example, Dr. Nezam Afdhal, Professor of Medicine at Harvard, told the sales force "the cost is driven down because there is no side effect management" and "the biggest challenge is patients not believing that they are on drug, because they have no side effects."

75. The high cost of Sovaldi caused other issues. Initially, insurance providers were not expecting Sovaldi's high cost, and after it was first launched Gilead was in a panic to get as

many prescriptions secured before insurance companies started requiring cost-saving tools such as prior authorization for the drugs. According to Relator, due to the high cost of these drugs, Gilead wanted as many prescriptions approved before insurance companies realized the enormous cost and made it harder to obtain coverage. This, in large part, is why Gilead placed so much emphasis on promoting Sovaldi almost six months prior to its FDA approval because it only had a limited time that insurance companies would allow coverage before scrutinizing these claims.

76. According to Relator, it was Gilead's intent to exhaust all the funds Medicaid and other government healthcare programs had allocated for prescription medications. And Gilead was successful in accomplishing this. For example, in California:

> Medi-Cal provides health care coverage for nearly one-third of Californians. Combined with the California Public Employees' Retirement System (CalPERS), ADAP, state hospitals, and corrections, taxpayer liability for increasing drug costs is significant. According to a December 2015 report published by the U.S. Senate Committee on Finance, Medi-Cal's fee-for-service (FFS) system alone spent nearly **$25 million** treating roughly **340 patients** with **Sovaldi and Harvoni in 2014**. However, Medi-Cal FFS is only a fraction of the Medi-Cal population. According to DHCS, private health plans invoiced the state an additional **$387.5 million** for **Sovaldi and Harvoni** treatments for Medi-Cal managed care enrollees between **July 2014 and November 2015** (for **3,624 patients**). Additionally, as a direct result of Sovaldi and Harvoni pricing, the 2015-16 California State Budget allocated $228 million just for high cost drugs to DHCS and the California Department of Corrections and Rehabilitation. In December 2015, it was reported that CalPERS spent $438 million on specialty drugs, an increase of 32% from the previous year. This represents one quarter of the total drug costs paid by CalPERS, while only 1% of the prescriptions filled.

SB 1010, Assembly Committee on Health, California State Assembly (June 21, 2016) (Comments, § 2(d)) (emphasis added).

C. Pre-FDA Approval Drug Promotion

i. Sovaldi

77. Gilead engaged in substantial marketing of Sovaldi prior to receiving FDA approval. According to Relator, at Sovaldi sales training, which occurred six months prior to the

FDA's approval of Sovaldi, Gilead trained its sales force to promote Sovaldi to providers prior to the drug's launch. Pursuant to federal regulations, prior to the FDA's approval of a new drug, the manufacturer is prohibited from making "promotional claims of safety or effectiveness of the drug for a use for which it is under investigation" and "commercialization of the drug before it is approved for commercial distribution." 21 C.F.R. § 312.7.

78. The Sovaldi sales force was hired approximately six months prior to the FDA's approval of Sovaldi despite the fact that they were hired solely to promote Sovaldi, and no other product in 2013. Gilead purportedly hired the sales force so far in advance to promote the hepatitis-C disease state, create physician target lists, document physicians' answers to Gilead questions (discussed below), prepare continuing medical education programs related to HCV, and find "Key Opinion Leaders" to serve as speakers until Sovaldi gained FDA approval. However, Relator quickly learned that this was not Gilead's intent. Rather, Gilead intended its sales force to promote Sovaldi prior to the FDA's approval and therefore create a market for the drug the first day it was approved.

79. Gilead trained its sales force to promote Sovaldi months before the drug received FDA approval. During home phase of sales training, which occurred approximately six months prior to Sovaldi's FDA approval, sales representatives were provided product and disease state binders, training modules, and online assessments.

80. Further, Gilead provided sales representatives with IMS prescribing data and instructed them to use the data to create their own target lists consisting mainly of "early adopters," which are physicians who would prescribe Sovaldi as soon as the drug was approved. These target lists were then used for the purpose of developing each sales representative's sales goals and incentive compensation. Once these early adopters had been identified, sales representatives

researched the provider to make sure they were still actively practicing and then assigned them a decile between .1 and .9 to represent their value to Gilead. Gilead senior management then deployed the sales force to call on these physicians to promote Sovaldi and try to develop them as speakers for Sovaldi's speaker program.

81. In order to receive 100% of the pre-launch compensation plan, Gilead required its sales representatives to have completed their target lists and called on every physician on the list by September 15, 2013. Further, in connection with making the required sales calls, sales representatives were required to ask each targeted physician a series of questions and document their answers. Specifically, Gilead required its sales representatives to ask each targeted physician the following:

> "*What percentage of your time is spent managing HCV patients?*"
>
> "*Are you interested in expanding your HCV practice?*"
>
> "*How many HCV patients have you treated in last year?*"
>
> "*How many HCV patients are referred to you in a month?*"
>
> "*What percentage of HCV patients do you refer to specialists for treatment?*"
>
> "*What percentage of genotype 1 (GT1) patients are treatment experienced?*"
>
> "*What percentage of genotype 2 (GT2) and genotype 3 (GT3) patients are treatment naïve?*"
>
> "*What percentage of your treatment naive patients are biopsied?*"
>
> "*What percentage of your treated patients had moderate fibrosis?*"
>
> "*What is the number of identified HCV patients in your practice today compared to 2 years ago?*"

82. Although sales representatives were required to ask each question listed above, it

was stressed during training that sales representatives absolutely had to ask each physician the first two questions listed above. Further, according to Relator, Gilead required its sales force to gather this information by September 15, 2013 so it could be used to persuade providers to prescribe Sovaldi, and later Harvoni.

83. According to Relator, answers to these questions were documented in sales representatives' Gilead provided IPads. At the end of every day, sales representatives had to document their call notes on their IPads. In the call note section, there was a space to document each physician's answers to these questions.

84. According to Relator, the true purpose of deploying the sales force prior to the FDA's approval of Sovaldi was not to provide HCV disease state education, but rather to promote Sovaldi to ensure a lot of physicians wrote Sovaldi prescriptions the first day the drug was approved. In sales training, Gilead management referred to this as "warehousing" or "corralling" patients so that providers could "put the pen to the pad" on day one and prescribe Sovaldi. For example, the physicians that sales representatives were supposed to be calling on were derived from IMS data and therefore these physicians were already treating HCV patients. These targeted physicians were HCV experts, or at least were well-versed in the treatment of HCV, and therefore could not benefit from a sales call to promote the HCV disease state. Rather, the only information that was of any use to these physicians was in regards to Sovaldi. In addition, when calling on these physicians, Gilead instructed sales representatives to instruct providers to perform their patients' laboratory work, fibrosis score, and urine analysis prior to the drug's approval so they could prescribe Sovaldi on day one. In addition, sales representatives were instructed, in submitting their expense reports, to state the expenditures were for HCV disease state promotion, and not Sovaldi because it had not been approved.

85. The physician speakers identified by sales representatives also helped Gilead promote Sovaldi prior to its FDA approval. The pre-launch speakers were provided slide decks to use during their presentations that focused solely on the HCV disease state. However, Gilead allowed speakers to insert their own slides into the slide decks. According to Relator, in many cases, the speakers added slides that contained information outside of the HVC disease state.

86. Several of the speakers selected by Gilead were also involved in the research and clinical studies for Sovaldi and they would regularly speak in detail about their experiences in the clinical trials. Therefore, Gilead knew that these speakers could discuss Sovaldi in a very detailed manner and that using such speakers would prompt Sovaldi-specific questions from the audience. In addition, all of the physicians who attended these speaker programs were already treating HCV patients, and therefore did not need education about the HCV disease state. Rather, according to Relator, physicians who attended these speaker programs were only interested in information regarding the new drug, Sovaldi and *not* HCV. For example, these speaker programs would be on subjects such as "treating relapsers and first responders" and "managing side effects" which Relator asserts provided no new or useful information to a physician experienced in treating HCV patients. According to Relator, at nearly every pre-launch speaker program, the conversation would quickly shift from a discussion of the HCV disease state to Sovaldi. Relator believes that this was Gilead's intended result because all of the speakers who sales representatives called on and attended these speaker programs were already high prescribers of HCV medication, and therefore already knew the basic disease state information. Thus, Gilead expected these physicians to prompt discussions of Sovaldi by asking questions because that was the only useful information to them. Further, Gilead permitted sales representatives and other Gilead staff to attend these speaker programs, and therefore had to have at least witnessed that at nearly every event the

discussion transitioned to Sovaldi.

87. Gilead, during its November Sovaldi pre-launch meeting, also provided sales representatives with a significant amount of Sovaldi specific promotional materials and training so its sales representatives could aggressively promote the drug prior to the drug's FDA approval. First, Gilead provided sales representatives with five clinical studies that supported Sovaldi's efficacy message. The five studies were NEUTRINO, FISSION, FUSION, AND POSITRON (published in the *New England Journal of Medicine*) and VALENCE (poster presented at AASLD in Washington, DC on November 1, 2013).

88. Further, Gilead trained sales representatives to present these studies using the SOAP method. The SOAP method is used by health care professionals to organize patient case notes and medical information into four categories: subjective information, objective information, patient assessment, and treatment plan. The SOAP training worksheet states that the five studies mentioned above were not expected to be approved for promotional use at the time of initial FDA approval of Sovaldi, and therefore sales representatives should not use these studies in the field. However, according to Relator, Gilead intended sales representatives to promote these studies to physicians nonetheless.

89. Second, prior to FDA approval, the sales force was provided an "unbranded" spiral bound version of the Sovaldi Package Insert for promotional use. In addition, Gilead trained sales representatives to identify "early adopters" or, in other words, physicians who would be likely to prescribe Sovaldi as soon as it was approved. Gilead also provided a HCP Profile training worksheet for this. Significantly, Gilead also trained its Sovaldi sales force on Support Path, and how to pitch the program's services to physicians. Support Path is a program designed to assist providers, mainly with coverage issues, in connection with prescribing their patients to Sovaldi or

Harvoni, not HCV disease state information.

90. Further demonstrating Gilead's intent to promote Sovaldi pre-FDA approval is the fact that at least two months prior to the launch of Sovaldi, Gilead hired, trained and deployed to physician's offices, a team of nurse educators (discussed in more detail, below).

91. According to Relator, Gilead's scheme to market Sovaldi pre-approval was due in large part to the drug's high cost. Gilead foresaw that Sovaldi's high cost would ultimately cause insurance providers to put cost saving measures in place, such as prior authorization, before they would pay for the drug. However, Gilead knew that it would take insurance providers a few months after Sovaldi was released to realize its high cost and implement such cost saving measures. Therefore, Gilead engaged in its scheme to promote Sovaldi pre-approval to get as many prescriptions covered before insurance companies started scrutinizing its claims more carefully.

92. For example, at the Sovaldi launch meeting in November 2013, Relator heard his manager, Brad Peacock, say that "right now the flood gates are open, slip as many prescriptions past the goalie as we can before they [payors] shut it down." This message – that Gilead had a limited amount of time to get prescriptions approved before insurance companies limited coverage – was also reiterated by Oriana Wiklund, the Western Region Sales Director. According to Relator, Gilead senior managers repeatedly referred to the time immediately following Sovaldi's launch as the "wild west" because the payors were caught off guard by the high price and initially had no coverage restrictions in place. Gilead openly discussed that the sales force should take advantage of the several months immediately following Sovaldi's launch before insurance providers could establish guidelines and coverage restrictions.

93. Gilead's scheme to promote Sovaldi pre-launch was very successful. According to Relator, a significant number of Sovaldi prescriptions were submitted on the day the drug was

approved by the FDA. In fact, Gilead praised Relator because one of the physicians in his territory was the first to prescribe Sovaldi, and even submitted the prescription before 9 am on the day the drug was approved. In addition, some providers even submitted Sovaldi prescriptions prior to the drug's approval.

ii. Harvoni

94. Beginning in September 2014, Gilead trained its sales force to promote Harvoni to physicians for the treatment of HCV. Gilead's Harvoni pre-launch marketing strategy was focused on differentiating Harvoni from the rest of the HCV market by boasting its 8-week duration, superior SVR rates, and interferon-free one pill dosing. According to Relator, Gilead instructed its sales force to hold mandatory physician speaker programs within their sales territories to promote Harvoni. In order to drive attendance, sales representatives informed the physicians that the speaker program would provide new information regarding a new 8-week, interferon free, treatment for HCV. This program description tipped off physicians that these programs were focused on Harvoni and resulted in attendees asking questions about Harvoni during the program. The goal of this marketing scheme, according to Relator, was to develop Harvoni "early adopters" or physicians who would be ready and willing to prescribe Harvoni immediately upon its FDA approval.

95. According to Relator, Gilead used its speaker programs to promote Harvoni pre-FDA approval. During the Harvoni launch meeting, Gilead informed its sales force to start setting up speaker programs on the HCV disease state in anticipation of the Harvoni launch. However, Gilead had already been doing HCV disease state speaker presentations for well over a year, and providers were unwilling to attend similar speaker programs on the same topic by an unknown speaker. As a result, it was very hard for sales representatives to drive attendance at the speaker

programs.

96. In fact, Relator recalls contacting his Gilead manager, Brad Peacock, to request the cancellation of a speaker program in his territory because no physicians had agreed to attend. Relator explained to Peacock that he had repeatedly invited many physicians to attend the program but they all responded negatively because they had already attended several "Sovaldi" speaker programs and did not see any value in attending to another one. Relator had previously expressed to Peacock that it was hard to hold speaker programs because physicians were not attending because there was no new information presented. In response, Peacock stated "did you tell them there is new information regarding how it [Harvoni] is different?" Thus, Peacock was instructing Relator to discuss with physicians how Harvoni was different from Sovaldi, and these presentations would provide that new information. In fact, Peacock attended several sales calls with Relator prior to the FDA's approval of Harvoni, where Relator explained that the speaker programs would contain new information, and referenced the differences between Sovaldi and Harvoni. Peacock never reprimanded Relator for using this pitch, and indeed praised him for it.

D. Gilead and Specialty Pharmacies

97. Prior to the launch of Sovaldi, each sales representative was instructed to establish relationships with three specialty pharmacies to direct providers to send Sovaldi and Harvoni prescriptions to be filled. According to Relator, Gilead only expected sales representatives to primarily work with one specialty pharmacy but required them to list three separate pharmacies to avoid the appearance that they were directing business to a particular pharmacy. Thus, although each sales representative technically worked with three specialty pharmacies, they would direct a majority of the prescriptions they secured to only one of those pharmacies. Relator worked with Bioplus, Premier, and Walgreens. Bioplus was the primary specialty pharmacy Relator worked

with originally, and it provided RSS and the other services discussed herein for Sovaldi prescriptions. Bioplus would also send patients "goodie bags" and "stocking stuffer" type gifts that were unrelated to Sovaldi or Harvoni prescriptions. Later on, Relator worked primarily with Premier which provide the RSS and other services discussed herein for Sovaldi prescriptions. Lastly, Relator's third specialty pharmacy was Walgreens, which similarly provided the same services discussed herein. According to Relator, although he did not use Walgreens frequently, he would send them a prescription occasionally.

98. Initially, sales representatives would select specialty pharmacies that had good approval rates for Sovaldi and Harvoni, were well-versed in HCV, and who would make obtaining coverage for Sovaldi and Harvoni prescriptions a priority.

99. After the sales representatives selected the three specialty pharmacies they were going to work with, they were to provide the names of those pharmacies to physician speakers in their territories so they could promote them during speaker programs and schedule joint programs at providers' offices with the specialty pharmacies' sales representatives to direct prescriptions to the specialty pharmacy. According to Relator, Gilead wanted sales representatives to develop relationships with specialty pharmacies to give them more control over coverage issues such as prior authorizations. Indeed, according to Relator, representatives from the specialty pharmacy and Gilead sales representatives would make joint sales calls to physicians' offices so they could explain that the specialty pharmacy would handle all of the administrative responsibilities associated with prescribing the drug. According to Relator, one of the specialty pharmacies he worked with, Premier, would regularly send a representative with Relator on sales calls to physicians' offices.

100. Significantly, Gilead told its sales force that they should select specialty pharmacies

to work with that would perform RSS for Sovaldi prescriptions on behalf of provider's prescribing the drug. Gilead told its sales force that due to the high cost of Sovaldi that sales representatives should only select specialty pharmacies that were willing to go "the extra mile" in performing RSS for Sovaldi to ensure that the drug was approved. This was the major factor in determining which specialty pharmacies sales representatives selected to work with. Further, according to Relator, specialty pharmacy representatives were also actively seeking out Sovaldi sales representatives to secure their business due to the high cost of the drug.

101. Gilead instructed its sales force to only work with specialty pharmacies that agreed to provide the following services for Sovaldi prescriptions: (1) prior authorization; (2) benefits analysis; (3) coverage appeals; (4) patient assistance program foundation assistance for patients; (5) patient education and training, including patient follow-up until the therapy was completed; and (6) would report prescribing data to IMS. Significantly, for the prior authorization, benefit analysis, and coverage appeal services, Gilead instructed sales representatives to only work with specialty pharmacies that were willing to perform these services at a high level. In other words, Gilead only wanted their sales representatives to work with specialty pharmacies that would agree to do everything possible to get the Sovaldi prescription filled. This meant doing more for Sovaldi prescriptions than the pharmacy might do for other drugs. For example, Gilead did not want its sales representatives to work with specialty pharmacies that would stop after receiving a prior authorization denial. Rather, sales representatives were instructed to work with specialty pharmacies that agreed to continue trying to get the drug approved even if initially denied.

102. According to Relator, the three pharmacies he worked with all provided the services discussed above.

103. According to Relator, at the time Gilead instructed its sales force to select three

specialty pharmacies to work with, it was uncommon in the industry for specialty pharmacies to provide RSS. And, further, at the time there were no specialty pharmacies providing these services at the same high level as they agreed to provide for Sovaldi prescriptions for any other drug. However, as discussed above, specialty pharmacy representatives were actively seeking out Sovaldi sales representatives to convince them to direct prescriptions to their pharmacy due to the drug's high cost. According to Relator, Gilead management told the sales representatives that Sovaldi was one of the most expensive drugs on the market, and due to the high profit they would receive from filling Sovaldi prescriptions, all the specialty pharmacies will want to work with them and will do whatever they ask to secure their Sovaldi business. Therefore, Gilead management explained that most specialty pharmacies would be happy to provide these services at such a high level in return for Sovaldi prescriptions. According to Relator, this was correct, and nearly every specialty pharmacy agreed to, and did in fact, provide the services discussed above, and at a high level.

104. After sales representatives found three specialty pharmacies that were willing to go the "extra mile" to ensure the drug was approved, sales representatives were instructed to, and did in fact, direct physicians prescribing Sovaldi to send their prescriptions to one of the three pharmacies. A representative from the selected specialty pharmacy would call on providers' offices. During these sales calls, the specialty pharmacy representative would explain to the provider that if they sent the prescription to their specialty pharmacy, they would perform all of the administrative responsibilities associated with getting the prescription filled. This eased the concerns of many providers who were apprehensive about prescribing Sovaldi due to the associated administrative responsibilities and concerns regarding their ability to get the drug covered by insurance.

105. Further, sales representatives were required to provide the names of the three specialty pharmacies to physician speakers in their territories so they could direct physicians in the audience to send their Sovaldi prescriptions to one of these specialty pharmacies.

106. This conduct violates the AKS because the specialty pharmacies are paying remuneration in exchange for referrals. That is, specialty pharmacies are providing Gilead in-kind remuneration by performing the administrative responsibilities associated with obtaining coverage of Sovaldi and Harvoni for patients. Even more, the specialty pharmacies agreed to "go the extra mile" when providing these services. And in exchange for providing such services, Gilead sales representatives and physician speakers directed Sovaldi and Harvoni prescriptions to those specialty pharmacies.

107. As explained herein, Sovaldi and Harvoni are very expensive medications and as a result, insurance providers, including government healthcare programs, have strict coverage requirements and scrutinize Sovaldi and Harvoni prescriptions to ensure the coverage requirements are met. According to Relator, Sovaldi and Harvoni were among the most complicated and hardest drugs to get approved from insurance providers. Specialty pharmacies, in return for sales representatives sending them prescriptions, performed the tasks associated with obtaining coverage because their staffs were more experienced in the approval process than a provider's staff, and therefore more likely to get the drug approved.

108. That specialty pharmacies were willing to provide RSS was critical. For example, according to Relator, and reflected in a spreadsheet in his possession, in August, 2014 there were approximately 36 providers who made 107 requests for RSS. In the Northwest Region, there were 256 providers who made 1,289 requests for such services.

109. According to Relator, another important factor in determining which specialty

pharmacy to work with was their ability and willingness to oppose therapeutic substitutions of Sovaldi or Harvoni, for less expensive treatment options. According to Relator, specialty pharmacies will call the prescribing physician when cheaper alternative treatment options are available to see if it is okay to substitute the drug prescribed. This was a significant concern given the high cost of Sovaldi and Harvoni. And, in fact, Relator's manager, Brad Peacock, instructed him not to work with specialty pharmacies that allowed therapeutic substitutions. Directing or refusing to deal with a pharmacy unless it agrees not to dispense therapeutic substitutions violates the AKS.

110. Specifically, Gilead was concerned that Olysio would be substituted for Sovaldi, which is approximately $20,000 less expensive than Sovaldi, and Viekira Pak would be substituted for Harvoni, approximately $10,000 less expensive than Harvoni.

111. As such, Gilead continued to send prescriptions to specialty pharmacies that opposed therapeutic substitution of its drugs. Further, when a provider failed to indicate his/her preferred specialty pharmacy on the enrollment form, Gilead would send the prescription to specialty pharmacies that would oppose therapeutic substitution of Sovaldi and Harvoni.

112. In anticipation of the FDA approval of Abbvie's Viekira Pak, an interferon free competitor to Sovaldi and Harvoni, with similar SVR rates, but significantly less expensive, Gilead mandated that sales representatives were no longer permitted to work directly with specialty pharmacies. Rather, in order to give Gilead direct control over the providers' specialty pharmacy selection, sales representatives were now tasked with building relationships with specialty pharmacies. According to Relator, the enrollment form filled out by providers had a section where the provider could indicate his/her preferred specialty pharmacy and whether therapeutic substitution was permitted. Gilead would then send this form directly to the specialty pharmacy

in the area. According to Relator, there was a lot of internal conversations at Gilead regarding not letting the insurance providers pressure the specialty pharmacy to switch treatments due to formulary status, and wanted physicians to write on the prescriptions "dispense as written" to oppose therapeutic substitutions. Relator believes that the Support Path representatives would coach providers to write "dispense as written" or "no therapeutic substitutions" on the enrollment form.

113. According to Relator, in opposing therapeutic substitution or alternative treatments to Sovaldi or Harvoni, the specialty pharmacy's staff would review clinical information and other evidence to support their assertion that patients should not substitute a cheaper alternative for these drugs. Then, the specialty pharmacy representative would tell the patient that "in my clinical opinion you should stay with Harvoni or Sovaldi."

114. After Relator left Gilead, he became Director of Marketing for a specialty pharmacy in Los Angeles, California. In this position, Relator has been contacted several times by the Support Path representative in his territory (who is unaware that Relator previous worked for Gilead) who stated to Relator:

> We handle the prior authorization process for the physicians, and a lot of them come over to us without the preferred pharmacy box filled in. If we work together, I will make sure all the Harvoni and Sovaldi scripts get filled through you.

115. According to Relator, the Support Path representative, by asking if they can "work together" was implying that in return for sending all of the Sovaldi and Harvoni prescriptions in that territory to Relator's specialty pharmacy, the pharmacy would oppose therapeutic substitutions or alternative treatments. It is important to note that according to Relator, the Support Path representative, in asking if they could "work together," was asking more than to oppose therapeutic substitutions.

E. Nurse Educators

116. According to Relator, Gilead had nurse educators, who were hired through Healthstar CES, a third party. Nurse educators provided education and training on the hepatitis-C disease state, side effect management, dietary information, and the actual administration of Sovaldi and Harvoni, among other things. Further, nurse educators would also connect patients with support groups or patient advocacy groups. According to Relator, Gilead's nurse educators provided both direct-to-patient education and training and "train the trainer" services. These education and training sessions included both branded and unbranded discussions. Further, as part of the education and training, the nurse educators would provide valuable educational resources as well as branded starter kits for the drug they prescribed.

117. Gilead's nurse educators also handled patients' follow-up questions after receiving the education and being prescribed the drug. According to Relator, patients could contact nurse educators after starting their HVC medication regimen with any questions about their disease state or the medication. Gilead's nurse educators would tell the provider that they would only answer basic patient questions, to prevent the patients from bothering the physician's staff with such questions, but if a serious issue arose they would instruct the patient to immediately contact their provider.

118. The direct-to-patient education was conducted in the beneficiary' provider's office, and consisted of a one-on-one or group session between the patient(s) and the nurse educator. This was a valuable resource to providers which was intended to induce Harvoni and Sovaldi prescriptions. In the absence of Gilead's nurse educator, the provider's staff would have to spend time and resources educating and training patients on the hepatitis-C disease state and proper administration of Harvoni or Sovaldi. By prescribing Harvoni or Sovaldi, providers did not have

to expend their own resources to train and educate patients.

119. The follow-up services provided by Gilead's nurse educators were also a valuable resource. Nurse educators were available to answer patients' questions and address any issues they may experience after being prescribed to Sovaldi or Harvoni. Nurse educators would provide the patient with a phone number, and then the patient could contact the nurse educator directly with any issues they may have after starting their medication regimen. According to Relator, in pitching these services to providers, Gilead trained its sales force to portray the HCV patient as very needy, and therefore the nurse educators would relieve the providers' staff from having to spend time handling patient questions and issues after receiving the prescription and education.

120. Further, Gilead's nurse educators also provided "train-the-trainer" services. Train-the-trainer was a term used internally at Gilead and reflected education and training services nurse educators provided to a provider's staff. Although Gilead offered to have their own nurse educators provide this training to patients, some practices preferred their own staff perform the patient training. Therefore, Gilead would provide the training to a staff member, typically a nurse, who would then provide the education and training to the provider's patients. In pitching this service, the nurse educator would ask the provider to identify one member of its staff to be the hepatitis-C office expert. After this staff member was identified, the Gilead nurse educator would train this individual to provide hepatitis-C and Sovaldi or Harvoni education to the provider's patients. And after this training was complete, the provider would have a trained hepatitis-C expert on staff who could assist its patients with questions and issues regarding their disease state or medication. In the absence of Gilead's nurse educators' train-the-trainer services, the provider would be forced to hire a staff member with expert knowledge about the hepatitis-C disease state. However, these services were only provided to providers that prescribed Sovaldi or Harvoni.

121. The fact that Gilead even had nurse educators for Sovaldi and Harvoni demonstrates that its true intent in providing these services was to induce prescriptions, and not to educate patients. Both Harvoni and Sovaldi are tablets, and are only indicated to be administered once daily, with or without food. Thus, there is nothing complicated about how to properly administer Harvoni or Sovaldi. Indeed, no amount of education or training could increase compliance for patients who cannot properly follow the administration instructions for Harvoni or Sovaldi. Therefore, it would be unreasonable to believe that Gilead deployed its nurse educators to educate patients on the proper way to administer Harvoni or Sovaldi. Rather, the nurse educator services were in-kind remuneration intended to induce prescriptions of Sovaldi and Harvoni.

122. The nurse educators' services were promoted to providers by Sovaldi sales representatives. Gilead sales representatives would promote this service to providers by informing them that the nurse educators were a cost saving vehicle for the provider because having Gilead handle patient issues, rather than the provider, would allow their staff to spend time on other things. By providing the nurse educator services sales representatives would say to providers "look what else we do for you – other than prescribing it and putting in the patient's mouth, we do everything else for you!" Indeed, sales representatives were trained to tell physicians that the nurse educators would remove the "costly burden" of coaching the provider's HCV patients. And, of course, the nurse educators' services were only provided if the physician prescribed Sovaldi or Harvoni. Providers prescribing different drugs would have to devote their own staff to training patients and handling their issues.

F. Gilead Intended Nurse Educators to Be a Substantial Benefit to Physicians and Induce Prescriptions.

123. Gilead's nurse educator services alleviated prescribing physicians and their staffs from having to educate patients on HVC, Sovaldi or Harvoni, or deal with subsequent patient

questions or issues that may arise after the prescription is filled. Taken together, Gilead assumed control over some of the core functions physicians are supposed to provide their patients. Providers are responsible for properly educating their patients on the HCV disease state, drug administration, and to provide clinical advice in response to subsequent patient questions or issues that arise after starting treatment. These are core functions that physicians are supposed to provide, and it was never intended that a pharmaceutical manufacturer would directly insert itself into, and assume complete control over educating patients and managing patients' care after the drug is prescribed.

124. Gilead's assumption over these core provider functions, therefore, provided a significant benefit to providers. By allowing Gilead to assume control over these responsibilities, providers could devote resources, which were previously dedicated to coverage issues, patient education and post-prescription patient follow-up care, to other things, such as treating patients, to improve the practice's profitability. Gilead understood the substantial time commitment providers' staffs devote to performing these functions, and therefore offered to provide these services to induce providers to prescribe Sovaldi or Harvoni over a competitors' drug.

125. Physicians submit claims for the patients' office visits, during which the physician determines to prescribe the patient to a drug. These office visits are referred to as evaluation and management ("E/M") services, and are billed under CPT code 99211-99215 for existing patients, and CPT codes 99201-99205 for new patients. 99211 is normally used for healthy patients that do not require the physician to spend a lot of time examining or make any complicated medical decision associated with their care. According to CPT code 99211's description, these office visits typically last only five minutes. 99214 and 99215 are used to bill office visits for sicker patients, who present with problems of mild to severe severity. According to their CPT code description, office visits billed under 99214 typically last 25 minutes, and office visits billed under 99215

typically last 40 minutes.

126. Although exact rates may vary by location, generally these E/M codes are reimbursed at the following amounts: (a) 99211: $25; (b) 99212: $55; (c) 99213: $90; (d) 99214: $130; and (e) 99215: $180.

127. Pursuant to their provider contracts with government healthcare programs, providers are prohibited from charging patients for administrative tasks associated with patient care. Payment for administrative costs related to patient care are incorporated into the E/M payment for the physician office visit. Further, E/M payments are also intended to compensate for patient education and handling patient issues.

128. In addition, higher E/M codes, such as 99214 and 99215, are typically used by physicians for office visits with patients with chronic conditions, such as HCV patients being prescribed to Sovaldi and Harvoni. Therefore, upon information and belief, a majority of physicians prescribing their patients to Sovaldi and Harvoni were also submitting claims for E/M visits with code 99214 or 99215. Government healthcare programs provide significantly increased payment for office visits billed under these codes because there will be more administrative tasks involved with treating patients with chronic conditions than with treating relatively healthy patients. Thus, the E/M payments incorporate payment for patient education associated with patient care.

129. Gilead provided patient education to providers as an inducement to prescribe Sovaldi or Harvoni over other drugs. By doing this, Gilead allowed providers to receive the full E/M payment for their patients with HCV, a chronic condition, despite the fact that Gilead was actually performing some of the services incorporated into the E/M payment. This, in addition to the value these services provided to providers, results in a violation of the AKS.

130. As referenced above, Gilead's intent is demonstrated, in part, by the questions it required its sales representatives to ask every targeted physician more than two months prior to Sovaldi's launch. Specifically, Gilead required all sales representatives to create a physician target list and ask the following questions before September 15, 2013:

"*What percentage of your time is spent managing HCV patients?*"

"*Are you interested in expanding your HCV practice?*"

131. According to Relator, Gilead repeatedly mandated that sales representatives ask every targeted provider these two questions and document their responses prior to September 15, 2013. Both of these questions, however, concern the providers' potential need for the free nurse educator services that Gilead offered in connection with Sovaldi and Harvoni prescriptions. For example, "What percentage of your time is spent managing HCV patients?" relates directly to the amount of time providers spend educating the patient on HCV, the drugs prescribed, and managing any post-prescription patient issues or questions. Thus, by asking this question, Gilead was able to gauge how much value its nurse educator services would provide an individual provider.

132. The second question, "Are you interested in expanding your HCV practice?" is also directly related to the nurse educator services Gilead was providing. Specifically, if the provider could lessen the amount of time its staff "spent managing HCV patients" it could use those resources to expand their HCV practice. Thus, Gilead expected its free nurse educator services to provide a substantial value to providers, and intended this offer to induce providers to prescribe its drugs over competitors' drugs.

133. Further, these two questions were used in tandem by design. Obviously, almost every provider would be interested in expanding their HCV practice. Therefore, the intent of asking this question was not to determine whether the provider actually wanted to expand their

HCV practice. Rather, this question was designed to provide Gilead with information regarding how valuable its services would be to a specific provider.

134. Further, some of the other questions Gilead required sales representatives to ask physicians during sales calls prior to September 15, 2013 also allowed Gilead to gauge how valuable its nurse educator services would be to targeted physicians. For example, sales representatives were required to ask providers:

"*How many HCV patients have you treated in last year?*"

"*How many HCV patients are referred to you in a month?*"

"*What is the number of identified HCV patients in your practice today compared to 2 years ago?*"

135. These questions directly relate to the number of HCV patients the provider is currently treating, which similarly correlates to how valuable Gilead's nurse educator services would be to that physician. As nurse educator services must be provided for every HCV patient, regardless of the drug prescribed, the more HCV patients a provider is treating directly correlates to how valuable Gilead's services will be to the provider.

136. Further, the second and third questions also try to determine the number of new HCV patients a provider is treating. Specifically, "how many HCV patients are referred to you in a month" is meant to gauge the number of new patients a provider treats over a short period. Similarly, "What is the number of identified HCV patients in your practice today compared to 2 years ago?" seeks to determine the number of new HCV patients the provider treats over an extended period. Similarly, and as stated above, sales representatives were required to ask "*What percentage of genotype 1 (GT1) patients are treatment experienced?*" and "*What percentage of genotype 2 (GT2) and genotype 3 (GT3) patients are treatment naïve?*" both try to determine the number of new HCV patients the provider treats.

137. These questions are asked because new patients require much more extensive HCV disease state education, unlike previously treated patients who would have received this education previously. New patients, who are unfamiliar with the HCV disease state or HCV medications, are much more likely to have questions or experience issues related to their treatment after receiving their HCV prescription. Therefore, Gilead, by requiring its sales representatives to ask these questions, demonstrated its intent was to identify the providers who would most benefit from the nurse educator services it provided, and offer those services as an inducement for Sovaldi and Harvoni prescriptions.

G. Unlawful Use of Patient Assistant Foundations

138. According to Relator, Gilead donated large sums of money to the PAN Foundation, and other similar foundations, which provides a patient assistance program ("PAP"), to purportedly provide financial assistance to patients who cannot afford the cost of their medications. PAPs have long been the subject of OIG scrutiny because they present a high risk of fraud under the AKS. Specifically, OIG has stated:

> . . . cost-sharing subsidies can be very profitable for manufacturers, providing additional incentives for abuse. So long as the manufacturer's sales price for the product exceeds its marginal variable costs plus the amount of the cost-sharing assistance, the manufacturer makes a profit. These profits can be considerable, especially for expensive drugs for chronic conditions. We are concerned that pharmaceutical manufacturers may seek improperly to maximize these profits by creating sham "independent" charities to operate PAPs; by colluding with independent charity programs to ensure that the manufacturer's contributions only or primarily benefit patients using its products . . . .

70 Fed. Reg. 70623, 70626 (Nov. 22, 2005).

139. Further, OIG's guidance states that financial donations by a pharmaceutical manufacturer to a bona fide charitable assistance program does not raise compliance concerns under the AKS if:

> (i) Neither the pharmaceutical manufacturer nor any affiliate of the manufacturer (including, without limitation, any employee, agent, officer, shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)) exerts any direct or indirect influence or control over the charity or the subsidy program;
>
> (ii) The charity awards assistance in a truly independent manner that severs any link between the pharmaceutical manufacturer's funding and the beneficiary (i.e., the assistance provided to the beneficiary cannot be attributed to the donating pharmaceutical manufacturer);
>
> (iii) The charity awards assistance without regard to the pharmaceutical manufacturer's interests and without regard to the beneficiary's choice of product, provider, practitioner, supplier, or Part D drug plan;
>
> (iv) The charity provides assistance based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner; and
>
> (v) The pharmaceutical manufacturer does not solicit or receive data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products.
>
> Simply put, the independent charity PAP **must not function as a conduit for payments by the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries' drug choices**.

Id. (emphasis added).

140. In 2014, OIG released a Supplemental Special Advisory Bulletin: Independent Charity Patient Assistant Programs. 79 Fed. Reg. 31120 (May 30, 2014). The OIG's 2014 guidance focuses primarily on the conduct of the PAPs. However, and relevant to this matter, OIG addressed donors who attempt to correlate their donations to PAPs with support for their own products. Specifically, OIG stated:

> Thus far, this Supplemental Bulletin has focused on the conduct of Independent Charity PAPs . . . . For example, an advisory opinion issued to an independent charity regarding the PAP it operates typically states that the charity has certified that it will provide donors only with reports including data such as the aggregate number of applicants for assistance, the aggregate number of patients qualifying for assistance, and the aggregate amount disbursed from the fund during that reporting period. Thus, the charity would not give a donor any information that would enable

> a donor to correlate the amount or frequency of its donations with the number of aid recipients who use its products or services or the volume of those products supported by the PAP. **The procedures described in these certifications are a critical safeguard and a material fact upon which we have relied in issuing favorable advisory opinions regarding Independent Charity PAPs. These opinions do not address actions by donors to correlate their funding of PAPs with support for their own products. Such actions may be indicative of a donor's intent to channel its financial support to copayments of its own products, which would implicate the anti-kickback statute.**

Id. at 31123. (emphasis added).

141. Gilead is using the PAN Foundation as a conduit to provide financial assistance to patients prescribed to Sovaldi and Harvoni. In other words, Gilead is using the PAN Foundation to do indirectly what it cannot do directly – provide financial assistance to patients for Harvoni or Sovaldi prescriptions. As discussed below, Gilead's financial support to the PAN Foundation, and other PAPs, was intended to channel financial support for its own products, in violation of the AKS.

142. During sales training, "foundation support," through the PAN Foundation, was discussed. Gilead explained that sales representatives were to inform providers about the PAN Foundation and explain how the foundation could help patients receive financial support for the copay cost of their Sovaldi or Harvoni prescriptions. Further, sales representatives were instructed to inform providers that the PAN Foundation would also provide financial assistance for medical procedures, such as liver biopsies. Gilead also instructed sales representatives to promote that, through Support Path, Gilead would work directly with the patient to make sure the correct information was provided to the Foundation to receive financial assistance. According to Relator, sales representatives would offer Support Path to help patients sign up for financial assistance through the PAN Foundation to relieve the provider of this burden. Further, Support Path would only provide foundation sign-up assistance to patients who would receive financial support

through the foundation for Gilead medications, Sovaldi and Harvoni. And, according to Relator, almost all patients who signed up for foundation support received financial assistance for their Sovaldi or Harvoni prescriptions. Thus, the fact that Support Path would only assist patients to obtain foundation support for Gilead drugs, and nearly every patient received financial assistance, suggests that Gilead was using foundation support "as a conduit for payments by the pharmaceutical manufacturer to patients."

143. During training, sales representatives were told that Gilead donates a lot of money to the PAN Foundation, and other similar foundations, as a way of mitigating providers' concerns regarding the cost of Sovaldi. Further, sales representatives were shown a bar graph which showed how much each major pharmaceutical manufacturer donated to the PAN Foundation. Of the major pharmaceutical manufacturers, Gilead had donated the most. In presenting the bar graph, the Gilead speaker stated that Gilead donates a significant amount to the PAN Foundation to ensure coverage of Sovaldi and Harvoni prescriptions, and sales representatives should feel good knowing that they are supported in the field unlike sales representatives from other companies.

144. Sales representatives were also told that Gilead spends a lot of time and energy analyzing the amount of money the Foundation would need to provide financial assistance for Sovaldi and Harvoni until the end of the year and use that information to determine how much to donate. Further, Relator's manager, Brad Peacock, stated that providers should be encouraged to prescribe early in the year because most of the time the foundation exhausted its funds for Sovaldi and Harvoni prescriptions by the start of the fourth quarter. This messaging also correlated to Gilead's scheme to promote Sovaldi prior to FDA-approval because it also encouraged providers to prescribe the drug early, thereby allowing Gilead to get as many prescriptions approved before insurance companies implemented cost saving measures.

145. Although presumably some of the funds Gilead donated to the PAN Foundation were used to provide financial assistance for things other than Sovaldi or Harvoni prescriptions, the clear intent of Gilead in making these contributions was to ensure financial support was provided for Sovaldi or Harvoni prescriptions while taking advantage of the much needed positive impact charitable giving had on their public image. Further, Gilead instructed its sales representatives to use the PAN Foundation as a marketing tool, demonstrating the Company's intent was to induce prescriptions by providing financial support for its own drugs through a third-party, and not to help those in need of financial assistance. Significantly, through the bar graph and training sessions, Gilead showed sales representatives a direct correlation between how much it donates to the foundation, and financial assistance provided for its drugs. Thus, it is clear that Gilead used the PAN Foundation, and other foundations, to induce prescriptions by providing financial support for its drugs.

146. The high cost of Sovaldi and Harvoni also made the offer of foundation support a powerful tool to induce prescriptions. As discussed herein, Sovaldi and Harvoni are very expensive, as are similar drugs that treat HCV. For many patients, the copay alone on these drugs are thousands of dollars. According to Relator, many physicians had concerns about their patients' ability to afford these drugs. In response to such a concern, Gilead sales representatives would explain that by prescribing Sovaldi or Harvoni, they would likely be eligible for foundation support, and therefore the cost of the drug would be significantly less. Further, sales representatives were instructed to tell physicians that foundation support would result in their patients' deductibles being met so they would not have to pay medical costs for the rest of the year and would also pay for other treatments associated with HCV.

H. Speaker Program Used as a Kickback

147. Gilead used speaker programs to compensate physicians, in the form of honorarium and luxury vacations, for prescribing Sovaldi and Harvoni, in violation of the AKS. Physician speaker programs were central to Gilead's promotional campaign for Sovaldi and Harvoni. Relator, who was one of Gilead's top three sales representatives, has an intimate knowledge of Gilead's speaker program because, in his role, he worked with many of Gilead's frequently used speakers. Gilead started hiring physician speakers as early as six months prior to the FDA's approval of Sovaldi and continued after his departure from the Company. According to Relator, however, Gilead paid physician speakers to induce them to prescribe Sovaldi and Harvoni to their patients, and to reward high prescribing providers, and not to provide education to local providers.

148. As discussed in more detail below, Gilead's speaker program was simply a way to compensate physicians for prescribing Sovaldi and Harvoni. Gilead's speaker programs discussed basic HCV disease state information, which provided no useful or new information to physicians currently treating HCV patients. Speakers would also discuss Sovaldi and Harvoni, but physicians interested in information about the drugs only needed to attend one speaker program to gain this information. As a result, attendance at the speaker programs significantly decreased. However, even though attendance decreased, Gilead actually increased the number of speaker programs it would conduct, by requiring sales representatives to arrange for physicians to speak at breakfast, lunch and dinner over a one or two day period, so that the physician speaker could be compensated for two or three programs instead of one. Many of these speaker programs occurred in providers' offices, and were only attended by the provider and his/her office staff. Lastly, many of Gilead's speakers were relatively unknown physicians with no thought value to local providers. Therefore, many providers had no interest in attending these programs. Thus, the only reason to use these

unqualified providers as speakers was to compensate them for prescribing Sovaldi and Harvoni through luxurious travel to cities of their choice, and multiple paid speaking engagements.

149. Prior to the launch of Sovaldi, the Gilead speaker programs were purportedly supposed to cover the hepatitis-C disease state, and attending physicians would receive a continuing medical education credit for attending. Initially, Gilead hired well-known national "thought leaders" in the hepatitis-C disease state, however, as discussed in more detail below, Gilead soon started hiring lesser-known speakers to compensate them for prescribing Sovaldi and Harvoni.

150. According to Relator, initially, Gilead's speaker programs were well attended by physicians. However, attendance quickly plummeted. According to Relator, the drop in attendance was due to the fact that Gilead had already conducted numerous speaker programs in every territory, and therefore the speaker programs offered no new information for potential attendees and providers were not interested in attending additional speaker programs where the same information would be conveyed. However, despite the drop in attendance, and the lack of educational value these programs provided, Gilead continued, and indeed increased, its speaker program as a means to compensate physicians prescribing Sovaldi and Harvoni.

151. Specifically, Gilead mandated that sales representatives arrange for two or three speaking engagements for each speaker per day: preferably one at breakfast, one at lunch, and one at dinner. Relator recalls that the sales representatives were directed to "schedule a full gamut for the speakers to make it worth it for them." Relator believes that Gilead's primary intention for this direction was to provide remuneration for prescriptions without running the risk of paying speaker honoraria over fair market value ("FMV") per program. As attendance at these speaker programs had dramatically diminished, Relator did not understand why Gilead had decided to

increase the number of speaker programs, rather than decrease its speaker program. The honorarium paid by Gilead to physician speakers was remuneration for prescriptions because there is no other rational explanation for why Gilead would triple the amount of speaker programs they performed, on the same exact subjects, at a time when attendance at speaker programs was drastically decreasing.

152. According to Relator, the breakfast and lunch speaking programs were normally very, very lightly attended. Rather, the breakfast and lunch speaker programs, which were nicely catered, were held to provide additional compensation to the speaking physician. Typically, physician speakers would come to town for a dinner speaking program, but expected, as Gilead promised, to be paid for two or three speaking engagements. According to Relator, due to the low attendance, the breakfast and lunch engagements rarely followed a Gilead provided slide deck, as the dinner programs typically did. Although a slide deck was provided to the speaker, and sometimes it would be up on their computer screen, there was no actual presentation because these speaker events were largely conversational and had very little, if any, educational content discussed. In most cases, the physician speaker would simply sit with the Gilead sales representative in the provider's office and chat with the physician, nurses, and office staff as they ate lunch. Therefore, as these speaker programs were barely attended, and there was very little education provided, the only reason Gilead had to continue holding such programs, and indeed increase the number of speaking arrangements it held, was to compensate physicians prescribing its drugs.

153. For example, in early-to-mid- 2014, Gilead conducted a speaker program at Salem Gastro, located at 875 Oak, St. SE, Salem, OR. According to Relator, the physician speaker did not put on a presentation, but rather just sat in the lunch area, without ever speaking or giving a

presentation. According to Relator, despite not presenting, the physician speaker was still paid honorarium.

154. According to Relator, providers' offices were normally the location for the breakfast and lunch speaker programs. The process for arranging these physician speakers for three programs a day went as follows: the physician speaker would arrive in a specific territory to give a presentation. On the day the speaker arrived, they would first do a lunch speaker program at a physician's office, which would only be attended by the physician and his/her nurses and office staff. After the lunch program, the speaker would do a dinner speaker program, typically held at a restaurant. The dinner programs typically had worse attendance than the breakfast and lunch programs because, according to Relator, nobody wanted to come out at night to listen to the same information from an unknown speaker. The following morning, the physician speaker would perform a breakfast speaker program at a different physician's office. The breakfast speaker programs, similarly, were normally only attended by the physician from the office and his/her nurses and office staff.

155. The manner in which Gilead instructed sales representatives to schedule speaker programs demonstrates that Gilead's speaker program was merely a way to compensate physicians for prescribing Sovaldi and Harvoni. First, as stated above, attendance at these speaker events was low, and therefore there is no reason, other than to compensate the speakers for prescribing its drugs, to continue conducting these programs. Second, the breakfast and lunch programs were held in individual provider's offices. There is no reason to conduct two speaker programs in individual physicians' offices solely for the physicians and their staffs, especially considering that these providers were in the same territory as the other two speaker programs held the same day. Further, these in-office speaker programs barely contained an educational component, and

therefore Gilead cannot claim it held so many speaker programs in the name of education.

156. Relator brought it to the attention of his manager, Peacock, that these speaker programs were being conducted despite their very low attendance. Gilead typically asked for attending physicians to RSVP to the speaking event. Therefore, in many instances, Gilead knew the speaker programs would not be well attended, but held them, and compensated the speaking physician, nonetheless, even when no physicians attended the program and the physician did not speak. To deal with this issue, Peacock and Relator agreed that they would cancel any speaker program if they did not receive five RSVPs. This solution, however, did not solve the problem because, according to Relator, many times they would receive five RSVPs, however, these physicians would not attend the speaker program. Relator maintains that the only viable solution would have been to decrease the number of speaker programs required, but Gilead instead continued to measure the sales representatives by the number of speaker programs they held, in order to use the speaker honoraria as a vehicle to provide remuneration for prescriptions.

157. Gilead also used speakers who were not well-known thought leaders on treating hepatitis-C, and therefore local providers had no interest in hearing them speak. According to Relator, during the Sovaldi pre-launch period, Gilead primarily retained hepatitis-C "thought leaders" who were well known to physicians treating hepatitis-C patients. However, as time passed, Gilead started using less well-known speakers and some who were completely unqualified to give such educational presentations. There is no legitimate reason to pay unknown physicians as speakers unless the compensation is actually a kickback for prescriptions.

158. For example, on several occasions Relator was instructed by his manager, Brad Peacock, to use MD1 as a speaker. According to Relator, MD1 was selected as a speaker because he was a high prescriber of Sovaldi.

159. MD1 was from Atlanta, GA and specialized in internal medicine. According to Relator, MD1 was an unknown internist with no influential value to other physicians in Relator's territory. As a result, very few physicians attended speaker programs hosted by MD1, and despite the low attendance, Peacock kept insisting Relator use MD1 as a Gilead speaker. For example, MD1 did a presentation on January 2, 2014 in Redding California where only two administrative employees from a provider's office attended, and MD1 did not present the slide deck.

160. In 2013, between October and December, Gilead spent $24,900 on speaker fees and travel arrangements for MD1. Of that amount, MD1 was paid approximately $15,850 in honorarium for speaking. In 2014, Gilead spent $95,039.86 on speaker fees and travel arrangements for MD1. Of that amount, MD1 was paid approximately $76,125 in honorarium for speaking. In 2015, Gilead spent $111,148.59 on speaker fees and travel arrangements for MD1. Of that amount, MD1 was paid approximately $89,950 in honorarium for speaking. And in return for the speaker position, MD1, in 2014, submitted $2,127,093.17 worth of claims to Medicare Part D for Sovaldi and Harvoni, and of this amount, $1,737,973.21 was for Sovaldi.

161. MD1 was an unknown internist who did not specialize in an area likely to treat HCV patients, such as gastroenterology, infectious disease, or hepatology. Thus, physicians treating HCV patients did not view him as a thought leader and therefore had no interest in hearing him speak about HCV or the drugs. However, he was frequently paid by Gilead to speak because he was the top Sovaldi and Harvoni prescriber in the state of Georgia.

162. Further, many of the physicians who did attend these Sovaldi speaker programs were "non-target physicians." Gilead provided its sales representatives with target lists for physicians in their territories. For each physician on the target list, they were assigned a rank based upon the likelihood they could/would prescribe Sovaldi. This rank was based upon historical

prescribing data from those physicians, and was updated based upon information sales representatives learned in the field. As discussed in more detail below, many of the physicians who attended these speaker programs were non-target physicians, meaning they were either marked as such on Relator's target list or were not included on his target list at all. These physicians were either designated as non-target physicians, or left off the list completely, because Gilead did not want their sales representatives wasting time calling on physicians who would not prescribe Sovaldi or Harvoni.

163. The following are examples of speaker programs held in Relator's territory where there was little or no attendance:

a. MD 1 performed three speaker programs on January 2, 2014 in Redding, California. MD1 was paid $3,100 for the first presentation and no physicians attended. MD1 was paid $2,350 for the second presentation and no physicians attended. MD1 was paid $1,600 for the third presentation and only two physicians attended. On February 20, 2014, MD1 did two speaker presentations in Portland, OR. MD1 was paid $3,100 for the first presentation and only one physician attended. MD1 was paid $2,350 for the second presentation and only one physician attended. On April 24, 2014, MD1 did two speaker programs in Portland, OR. MD1 was paid $2,350 for the first presentation and only two physicians attended. MD1 was paid $1,600 for the second presentation and only two physicians attended. On June 4, 2014, MD1 was paid $800 for a speaker presentation in Bend, OR and no physicians attended. On June 5, 2014, MD did two speaker programs in Portland, OR. MD1 was paid $1,600 for the first presentation and only two physicians attended. MD1 was paid $3,100 for the

second presentation and only one physician attended.

b. MD2 performed two speaker presentations on October 10, 2013. MD2 was paid $2,500 for the first speaker program, conducted in Portland, OR, and only two physicians attended. MD2 was paid $1,750 for the second speaker program, conducted in Springfield, OR, and only one physician attended. Between September and December 2013, Gilead paid MD2 $43,950 for speaking and $348,994 for research. In the first half of 2014, Gilead paid MD2 $31,850 for speaking and $47,687 for research. And, in 2014, MD2 prescribed $1,940,837.20 of Sovaldi under Part D.

c. MD3 performed two speaker presentations on September 24, 2013. MD3 was paid $2,500 for the first speaker program, conducted in Springfield, OR, and only four non-target physicians attended. MD3 was paid $3,200 for the second speaker program, conducted in Portland, OR, and only two physicians attended.

d. MD4 performed two speaker presentations on November 19, 2013. MD4 was paid $2,500 for the first speaker program, conducted in Ashland, OR, and no physicians attended. MD4 was paid $2,500 for the second speaker program, conducted in Klamath Falls, OR, and only one, non-target physician attended. MD4 also performed two speaker presentations on April 8, 2014. MD4 was paid $2,500 for the first speaker program, conducted in Redding, CA and only two physicians attended. MD4 was paid $2,500 for the second speaker program, conducted in Yreka, CA, and only one, non-target physician attended. Between September and December 2013, Gilead paid MD4 $28,900 in speaking fees. In 2014, Gilead paid MD4 $47,900 in speaking fees. Also in 2014, MD4

prescribed $1,254,844.25 of Sovaldi reimbursed under Part D, and $447,008.16 of Harvoni reimbursed under Part D.

e. MD5 performed two speaker presentations on November 21, 2013. MD5 was paid $3,750 for the first speaker program, conducted in Eugene, OR, and only three non-target physicians attended. MD5 was paid $3,000 for the second speaker program, conducted in Portland, OR and only five physicians attended. Between September and December 2013, Gilead paid MD5 $38,050 in speaking fees. In 2014, Gilead paid MD5 $48,000 in speaking fees. In 2014, MD5 prescribed $371,871.16 of Sovaldi, reimbursed under Part D, and $1,376,970.65 of Harvoni, reimbursed under Part D.

f. MD6 performed a speaker program on July 23, 2014 in Medford, OR and only two physicians attended. MD6 was paid $3,000 for this presentation. Between September and December 2013, Gilead paid MD6 $38,850 in speaking fees. In 2014, Gilead paid MD6 $50,600 in speaking fees. In 2014, MD6 prescribed $2,345,063.52 of Sovaldi reimbursed under Part D.

g. MD7 performed a speaker program on August 19, 2014 in Portland, OR and only two physicians attended. MD7 was paid $3,000 for this presentation. From September to December 2013, Gilead paid MD7 $6,500 in Sovaldi speaking fees. In 2014, Gilead paid MD7 $78,350 for Sovaldi and Harvoni speaking engagements. In 2014, MD7 prescribed $3,210,234.14 of Sovaldi, reimbursed under Part D, and $719,249.85 of Harvoni, reimbursed under Part D.

164. As is shown above, despite the extremely low attendance at the physician speaker presentations, Gilead continued conducting regular speaker programs in the Northern California

and Oregon territories in order to induce and reward Sovaldi and Harvoni prescriptions.

165. According to Relator, Gilead also used the speaker programs as a vehicle to provide speakers with trips to vacation destinations. Specifically, Gilead would try to arrange for speakers to give presentations in locations they wanted to visit on vacation. For example, Gilead speaker NP1 was offered a trip to Alaska as part of her role as a speaker. According to Relator, NP1 was a nurse practitioner and Sovaldi speaker from Medford, Oregon who in 2014, was the top Sovaldi prescriber in the Medford area and the top five Sovaldi prescriber in the entire state of Oregon. Relator recalls his manager, Brad Peacock, stated "we want to keep NP1 happy. She wants to go to Alaska, so let's talk to the sales representatives there to see if they can use her." As Peacock made clear, the decision to send NP1 to Alaska was not based on a legitimate need for a speaker in that territory. Rather, it was intended to be a kickback in the form of travel expense to her desired location. Further, NP1 also expressed interest in visiting Wyoming, and, similarly, Gilead attempted to accommodate her travel request. However, as discussed below, NP1 expressed concerns regarding the cost of Sovaldi and Harvoni and as a result, Gilead only allowed her to speak to her own office staff. Therefore, Relator does not believe these trips ever materialized, but Relator is unsure because he left Gilead in October 2014.

166. On another occasion, Relator was privy to a discussion regarding MD1. According to Relator, MD1 came to Relator's territory in early January 2014 for a speaking engagement and asked him to schedule speaking arrangements for him near the Redwood Forest, which he had always wanted to visit but never had the opportunity, when the weather was optimal for visiting the Redwood Forest. Relator informed MD1 that the best time to visit the Redwood Forest was in October 2014. In June 2014, MD1 again asked Relator to schedule speaking engagements for him in October 2014 so he could visit the Redwood Forest while being paid as a "speaker," which also

included travel costs. Relator relayed MD1's request to his manager, Peacock, who instructed Relator to schedule MD1 to speak near the Redwood Forest in October 2014. Relator is not sure whether MD1 was provided with this trip because he left Gilead in October 2014.

167. Relator also overheard a conversation by Gilead managers discussing a physician speaker which Gilead arranged for speaker engagements in cities where the physician planned to travel for his child's college visits. According to Relator, this allowed Gilead to pay for the physician's travel expenses while visiting different cities to tour colleges.

168. Further, Relator states that similar conversations occurred with regard to other speakers and he overheard other Gilead managers joke about asking speakers where they would like to go this time of year, insinuating that the physician speakers were using the opportunities as a vacation and Gilead was willing to pay.

169. Gilead also compensated some mid-and-high-level prescribers, who were not influential enough to speak to other providers, by allowing them to speak to their own office staff. These speaker presentations were held either at a restaurant of the provider's choice or the provider's own office, and were only attended by the speaking physician's office staff. For example, NP1 was a speaker and high prescriber of Sovaldi. However, at a Harvoni pre-launch lunch, NP1 complained to Peacock about Sovaldi's high price and the anticipated high price of Harvoni. This resulted in an argument between NP1 and Peacock. According to Relator, after NP1 expressed her concerns, Peacock told Relator that he did not want NP1 doing any more speaker presentations because he did not want her to "spread the poison" to other prescribers. However, NP1 was a high prescriber of Sovaldi, and Gilead wanted to keep her happy so Peacock instructed Relator to allow NP1 to speak to her own office staff, but not other providers, at either her office or a restaurant of her choosing. According to Relator, on at least three occasions, NP1

was paid by Gilead to speak to her own office staff. One of these "speaker presentations" took place at NP1's own office. The other two presentations were held at RoxyAnn Winery, in Medford, Oregon, where NP1, again, spoke to her own staff, which consisted of non-prescribing medical assistants and office staff. According to Relator, this was intended to be a reward for the provider prescribing Gilead's drugs.

170. However, the practice of allowing speakers to speak to their own office staff was not only to prevent NP1 from spreading her concerns to other providers. Rather, before NP1 expressed concern regarding the drug's price, she was permitted to speak in front of her own office staff. For example, on December 16, 2013, NP1 spoke in Medford, Oregon. During this speaker presentation, which was held at Roxyann Winery in Medford, OR, no physicians attended, and NP1 simply spoke in front of her own office staff. According to Relator, NP1 was compensated for this speaker program. Further, Gilead regularly paid other providers to speak to their own office staff, as this practice was not confined to NP1.

171. Lastly, there are several providers referred to internally at Gilead as "Sovaldi Royalty." These physician speakers were regularly used throughout the country by Gilead. As a result, they were paid substantial speaking fees and also prescribed massive amounts of Sovaldi and Harvoni. These physicians include:

a. Gilead paid MD8 $47,750 for Sovaldi speaking engagements between September 2013 and December 2013. In 2014, Gilead paid MD8 $128,537.50 for Sovaldi and Harvoni speaking engagements. In 2014, MD8 prescribed $12,993,071.05 of Sovaldi, reimbursed by Part D, and $384,976.06 of Harvoni, reimbursed by Part D.

b. Gilead paid MD9 $11,450 for Sovaldi speaking engagements between

September 2013 and December 2013. In 2014, Gilead paid MD9 $99,200 for Sovaldi and Harvoni speaking engagements. In 2013, MD9 prescribed $421,701.98 of Sovaldi, reimbursed by Part D. In 2014, MD9 prescribed $10,289,311.92 of Sovaldi, reimbursed by Part D, and $4,976,728.48 of Harvoni, reimbursed by Part D.

c. Gilead paid MD10 $54,150 for Sovaldi speaking engagements between September 2013 and December 2013. In 2014, Gilead paid MD10 $76,600 for Sovaldi and Harvoni speaking engagements. In 2014, MD10 prescribed $8,418,478.83 of Sovaldi, reimbursed by Part D, and $994,487.71 of Harvoni, reimbursed by Part D.

d. Gilead paid MD11 $18,200 for Sovaldi speaking engagements between September 2013 and December 2013. In 2014, Gilead paid MD11 $89,100 for Sovaldi and Harvoni speaking engagements. In 2014, MD11 prescribed $6,050,438.56 of Sovaldi, reimbursed by Part D, and $883,557.50 of Harvoni, reimbursed by Part D.

172. According to Relator, Gilead was aware that Premier was paying its sales representatives to direct prescriptions to its pharmacy. However, upon information and belief, Gilead did not stop this practice because Premier's kickback scheme actually increased Sovaldi and Harvoni prescriptions because of their high reimbursement. In fact, in mid-to-late 2014, Gilead entered into a pricing contract with Premier that offered a volume-based margin on Harvoni and Sovaldi purchases, meaning that as Premier purchased more of their drugs, Gilead offered them a lower price, enabling Premier to increase their profit from the spread between the purchase price and the reimbursement received from government and commercial payers. Gilead's volume based

contract incentivized Premier to aggressively grow the number of Sovaldi and Harvoni prescriptions it filled each month.

I. Overstating Efficacy

173. According to Relator, Gilead trained its sales force to make material misrepresentations regarding Sovaldi's and Harvoni's efficacy.

i. SVR Rates for Treatment Naïve

174. The primary misrepresentation by Gilead is in regards to its purported SVR rates for hepatitis-C patients. Specifically, Gilead promoted over a 90% SVR rates for all genotype 1 ("GT1") patients without discussing that this overall GT1 SVR rate included only treatment naïve patients ("TNP"), and included no treatment experienced patients ("TEP"). TEP are patients who previously failed pegylated interferon and ribavirin therapy. In the United States, GT1 patients account for up to 73% of all patients with hepatitis-C ("HCV").

175. According to Relator, Gilead aggressively promoted SVR rates as high as 93% for GT1 patients without cirrhosis and 90% for GT1 patients "overall" SVR rates.

176. Following Sovaldi's FDA approval, Medicaid, Tricare, and Medicare initially covered Sovaldi for HCV patients with or without Cirrhosis (F-0 – F-4), however, after just a few months these government payors' required a prior authorization for Sovaldi that would only approve coverage for the patients with progressed HCV (F-3 – F-4). Because HCV is a slow progressing disease that can take four to five years to progress between phases (F-0 – F-4) and over twenty years to cause life threatening liver damage (F-4), the patients that government payors would approve are those patients who have had the disease for many years and who are likely to have failed previous treatments. Therefore, GT1 TEPs was a significant portion of Gilead's target population.

177. The 90% "overall" SVR rates touted by Gilead were false and misleading. First, Sovaldi's clinical trials did not include even a single GT1 TEP. In fact, in the entire Sovaldi approved FDA label, there is no mention of GT1 TEP. Further, the FDA's approval for Sovaldi was based on the results of six phase 3 clinical trials. Of the six clinical trials, only two evaluated GT1 patients, and all such patients were TNP. Specifically, the Neutrino study evaluated GT1 in TNP with HCV, and the Photon study evaluated GT1 patients with HCV/HIV coinfection.

178. Indeed, Sovaldi's own FDA approved package insert refutes Gilead's efficacy claims. Specifically, the package insert states:

> It is estimated that the SVR12 in patients who previously failed pegylated interferon and ribavirin therapy will approximate the observed SVR12 in NEUTRINO subjects with multiple baseline factors traditionally associated with a lower response to interferon-based treatment (Table 9). The SVR12 rate in the NEUTRINO trial in genotype 1 subjects with IL28B non-C/C alleles, HCV RNA greater than 800,000 IU/mL and Metavir F3/F4 fibrosis was 71% (37/52).

Sovaldi Package Insert, Section 14.2.

179. Thus, the Sovaldi package insert states that the estimated SVR rate in GT1 TEP would be the same as the patients in the Neutrino study with multiple baseline factors traditionally associated with a lower response to interferon based treatment. The multiple baseline factors associated with pegylated interferon and ribavirin failure are IL28B non-C/C alleles, HCV RNA greater than 800,000 IU/mL and Metavir F-3 – F-4 fibrosis. This estimate is 71% (37/52). However, the estimated 71% SVR for GT1 TEP was not contained in any of the Sovaldi promotional or marketing materials, and was not included in the Sovaldi marketing message, where the 90% overall and 93% non-cirrhotic SVR rates were promoted.

180. The 90% SVR rate was even more misleading given the method of testing used by Gilead. SVR is measured 12 or 24 week after the end of treatment by using quantitative viral load tests, known as test assays, which measure the amount of the HCV virus in one milliliter of blood.

Direct Acting Agents ("DAA"), like Sovaldi, are different from drugs such as Peg Interferon and Ribavirin because they are direct acting and do not continue to eradicate the virus beyond end of treatment ("EOT"), so if there is even one viral cell remaining after EOT, it may replicate and cause a relapse. Twelve weeks after patients stop taking Sovaldi, SVR is measured as either undetected (cured) or detected (failed). SVR undetected, or cured, means that the HCV virus may still be present, but is less than 15 international units ("IU") of the HCV virus per milliliter of blood.

181. The SVR +90% rate that Gilead promoted for Sovaldi are based on Phase 3 clinical trials. However, all of Gilead's phase III clinical trials used the COBAS TaqMan HCV test assay (version 2.0) to measure Serum HCV viral load values. This test assay has a lower limit of quantification (LLOQ) of 25 IU/mL, meaning that this test reports SVR undetected if there is less than 25 IU of the HCV virus per milliliter of blood. Thus, the 90% of patients Gilead considered to be "cured" in the clinical trials were really just undetected, meaning they had less than 25 IU/mL. In real world clinical practice, a viral load over 15 IU/mL is considered a treatment failure. For example, if at 12 weeks EOT with Sovaldi a patient's blood work shows 20 IU/mL, Gilead's clinical trials considered that patient to have achieved SVR-12 or "cure," while in real world clinical practice, this same patient would be considered a treatment failure. Had Gilead used test assays with similar sensitivity to those actually used in clinical practice, the overall SVR rate would have been considerably lower. Gilead, knowing that most providers would assume SVR meant less than 15 IU/ml, failed to inform them that for Sovaldi's clinical trials, SVR undetected was measured at less than 25 IU/ml, and not the industry standard. Thus, Gilead assumed that physicians would presume Gilead's purported SVR rates were based upon 15 UI/ml standard, making it appear even more effective than demonstrated in clinical studies.

182. Further, the largest real life retrospective analysis of Sovaldi to date, published in 2015, supports Relator's allegations that Gilead falsely presented the drug's SVR rates. Effectiveness of sofosbuvir-based regimens in genotype 1 and 2 hepatitis C virus infection in 4026 U.S. Veterans (June 26, 2015).[3] The analysis was conducted by the U.S. Department of Veterans Affairs, the largest integrated national provider of HCV care. The SVR of Sovaldi based regimens (12 weeks) was assessed in an observational, intent-to-treat cohort analysis of 4026 genotype 1 (N = 3203) and genotype 2 (N = 823) HCV-infected veterans. Investigators assessed clinical data from electronic medical records through the U.S. Department of Veterans Affairs. The results showed drastically lower SVR rates than the +90% SVR that Gilead's phase 3 Trials boasted and were only slightly better (if at all) than Peginterferon and Ribavirin (a quarter of the price). In the study, the SVR rates for GT1 were: 66.8% for patients taking Sovaldi, peginterferon, and ribavirin; 75.3% for patients taking Sovaldi and Olysio; and 74.1% for patients taking Sovaldi, Olysio, and ribavirin. Significantly, in the study one-third of the 3,023 GT1 patients treated with a Sovaldi-based therapy for 12-weeks were TEPs. The results showed that for GT1 patients treated with Sovaldi, peginterferon, and ribavirin, the SVR rates for TNP vs. TEP were significantly different: TNPs were 73.7% and TEPs were only 55.6%. Further, the study showed that GT1 patients with cirrhosis (i.e. F-Score of F3 –F4, which is the only patient population that Tricare and Medicaid covered via prior authorization) were significantly less likely to achieve SVR.

ii. <u>The Scheme</u>

183. At the July 2013 On-Boarding Meeting, Relator learned of Gilead's plan to roll out their new HCV "cure" drugs in phases. By using this promotional scheme, Gilead was able to treat some patients with both Sovaldi and Harvoni, despite the claims that both drugs "cure" HCV.

[3] *Available at* https://www.ncbi.nlm.nih.gov/pubmed/26113432.

184. The first phase involved the rollout of Sovaldi and was intended to test the market's reaction and willingness to pay for such a high priced drug. Knowing that Sovaldi's SVR, or cure rates, were not as high as advertised, Gilead's plan was to get as many patients prescribed to Sovaldi prior to the launch of Harvoni so Sovaldi treatment failures could be retreated with Harvoni.

185. Gilead experienced some pushback from providers who were waiting for an FDA approved HCV drug without interferon, such as Harvoni. And, as many of these providers knew Harvoni was close to approval, they questioned, especially given the high price of both drugs, why they should prescribe Sovaldi instead of waiting for Harvoni's approval. Physicians often pointed out that many HCV patients have had HCV for years with no complications and because it usually takes four to five years for the disease to progress between stages and twenty or more years to cause serious life threatening damage to the liver (decompensated liver cirrhosis), it made sense to wait for an FDA approved interferon free treatment.

186. To overcome this obstacle, Gilead trained its sales force to create doubt in the minds of providers about whether Harvoni would actually be approved and at what price. Gilead trained its sales representatives to promote a "treat now" message by informing physicians that Harvoni might be much more expensive, insurance providers may not cover the drug, and there was no guarantee the FDA was going to approve the drug. However, according to Relator, at the time this messaging was used, Gilead had already been informed by the FDA that Harvoni was going to be approved. Therefore, Gilead wanted physicians to prescribe Sovaldi right away so patients who were not "cured" could be retreated with Harvoni. Indeed, the sales message Gilead provided was "start in January, cured by spring!"

187. Gilead further instructed its sales representatives to tell physicians to conduct

laboratory work on their patients 12 weeks after completing either a twelve or twenty four week Sovaldi regimen. With previous HCV treatments, SVR (sustained virologic response) or "cure" was measured 24 weeks after end of treatment ("EOT"). However, because of Sovaldi's unique ability to "kill" the virus by preventing it from replicating, SVR could now be measured 12 weeks EOT ("SVR-12").

188. However, Gilead was aware that the SVR rates it promoted were misleading, and therefore expected that physicians would not realize the higher than expected treatment failures until the laboratory work was conducted, approximately six to nine months after Sovaldi was prescribed. These treatment failures allowed Gilead the opportunity to implement phase two of its scheme.

189. Phase two of Gilead's HCV drug rollout involved convincing physicians with patients that experienced treatment failure with Sovaldi, to now prescribe Harvoni to retreat these patients. Phase two was perfectly timed because, within six to nine months after Sovaldi's launch, just as providers were starting to see Sovaldi treatment failures, Harvoni was ready for launch. Indeed, Gilead trained sales representatives to respond to physician complaints about Sovaldi treatment failures by stating "don't worry doctor, the Holy Grail, Harvoni, is here." In this way, Gilead was able to have some patients treated with both Harvoni and Sovaldi, thereby increasing their profits.

190. When phase two was implemented, Gilead was also developing its new HCV drug Epclusa, the first and only all-oral, single tablet regimen approved to treat all HCV genotypes. In trying to convince physicians to retreat Sovaldi failures with Harvoni, Gilead expected some physicians to want to wait until Epclusa was launched to treat their patient with that drug. Similarly, Gilead instructed sales representatives to scare physicians by telling them that Epclusa

could be more expensive than Harvoni, and there was no guarantee that the drug would receive FDA approval. However, according to Relator, at the time this messaging was conveyed to the sales force, Gilead was intending on releasing Epclusa at a significantly reduced price compared to Sovaldi or Harvoni. Indeed, phase three, the launch of Epclusa, confirmed this as it was released at a significantly lower price than Sovaldi or Harvoni. Specifically, the cost of a twelve week regimen of Epclusa, at launch, was $74,760, compared to Sovaldi, $84,000, and Harvoni, $94,500.

iii. Promotion of the 90% Overall SVR Rates

191. According to Relator, Gilead provided its sales force with training materials, in-house training, sales message role play exercises, and promotion material to be used in the field to promote this false SVR efficacy message. During sales training, sales representatives were taught to tout Sovaldi's greater than 90% overall SVR rate. However, the training never discussed that the 90% SVR rate was from a study of only GT1 TNPs, that the SVR rates for GT1 TEP was based on an estimated SVR rate, or that the estimated SVR was only 71%. Further, the sales force was never told to specify that the SVR rates were found in TNPs only.

192. Gilead trained its sales representatives to mislead physicians who asked about the SVR rates for TEPs. One of the core messages used by sales representatives was that "there is no patient that you have that we do not have fantastic data on." However, this messaging is false and indicates Gilead's intent to promote false SVR rates because Gilead did not have data on GT1 TEPs. And, significantly, GT1 patients comprise a significant majority of the HCV patient population. Further, in November 2013, Relator attended an HCP profile training session which focused on addressing concerns of HCPs "who treat a lot of GT1 patients." During the training session, Gilead senior managers reviewed and role-played examples of physician probing questions and key product messages. The first HCP objection/concern on the training worksheet

was "Physicians has a high volume of patients who are treatment experience (TE)."

193. During this training session, sales representatives were instructed to tell providers who asked why Sovaldi clinical trials did not contain HCV GT1 TEPs that it was because these patients were already enrolled in Harvoni clinical trials. In reality, however, it was because including such patients in the clinical studies would significantly reduce the overall SVR rates for GT1 patients. Further, for physicians who specifically questioned the estimated SVR of Sovaldi in GT1 TEPs, sales representatives were instructed to tell them that for TEPs they could increase the treatment duration from 12 weeks to 24 weeks. Sales representatives were instructed to give this instruction to providers despite the fact that there is no FDA approved clinical data to support efficacy at 24 weeks for GT1 TEPs. In addition to the sales pitch, Gilead also provided sales representatives with marketing materials that boldly displayed the purported overall SVR rate of 90%.

194. Gilead also trained sales representatives to promote this misleading efficacy rate using the SOAP method (discussed above) to discuss clinical studies. Specifically, on November 13, 2013, Gilead conducted a SOAP poster session where Gilead sales managers taught sales representatives how to present clinical trial data to providers using the SOAP method. At the beginning of this training session, Gilead management stated that the clinical studies had not been approved, and therefore were for training purposes only and the studies should not be shared with providers. This same disclaimer is included on the SOAP worksheet discussed above. Immediately following this disclaimer, however, the sales trainers taught the sales force how to present the unapproved NUETRINO clinical trial data to providers using the SOAP method. According to Relator, it was during this training session that sales representatives were instructed to present misleading "overall" 90% SVR rate for Sovaldi.

J. Manipulation of Fibrosis Scores

195. Gilead encouraged its sales force to inform physicians that failure to abide by the dietary restrictions prior to a measure of their patients fibrosis score ("F-Score") would result in coverage of Sovaldi or Harvoni. This was done to fraudulently bypass insurance providers' coverage restrictions and fraudulently obtain coverage for Sovaldi and Harvoni. According to Relator, from December 2013 until March 2014, it was easy to get Sovaldi covered by insurance providers, including government healthcare programs. However, beginning in second quarter of 2014, insurance companies started scrutinizing and denying claims for Sovaldi. According to Relator, this is a result of the large and unexpected cost Sovaldi caused these providers in the previous months.

196. Thereafter, Medicare, Medicaid, Tricare, and other commercial insurance carriers implemented strict prior authorization criteria for Sovaldi and Harvoni. The new prior authorization criteria required all patients prescribed to either Sovaldi or Harvoni to have their fibrosis score tested before the insurance provider would approve coverage of the drug. Most insurance providers required patients have a fibrosis score of F-3 to F-4 to obtain coverage.

197. Fibrosis is a scarring process that replaces damaged liver cells. A normal liver is at a stage between F-0 and F-1. Stage F-2 denotes light fibrosis, and F-3 is severe fibrosis. "Cirrhosis" is defined from stage F-4, when scar tissue exists throughout the liver. F-score tests measure the severity of fibrosis by the amount of liver stiffness. Severity of fibrosis is classified into five stages, F-0 to F-4. F-0 means no fibrosis, F-1 is a mild fibrosis, F-2 is a moderate stage of fibrosis, F-3 is severe fibrosis, and F-4 is cirrhosis.

198. The two major fibrosis score testing devices are FibroSure and FibroScan. FibroSure is a patented biomarker test that uses the results of six blood serum tests to generate a

score that is correlated with the degree of liver damage in people with a variety of liver diseases. FibroSure has the same prognostic value as a liver biopsy. FibroScan uses elastography, a technique similar to ultrasound, to measure the stiffness of the liver. It is a non-invasive, painless alternative to liver biopsy measures the level of fibrosis in relation to the stiffness of the liver, so the harder the liver is, the more serious the fibrosis is likely to be.

199. Both FibroSure and FibroScan require that the patient refrain from eating at least two hours before the test is administered because digesting a meal causes the liver to appear cirrhotic. Therefore, a meal ingested within two hours of a liver exam can easily cause an F-1 or F-2 fibrosis patient to appear to be an F-3 or F-4 cirrhosis patient, falsely qualifying them for coverage of Sovaldi or Harvoni under government healthcare programs.

200. During the Sovaldi launch meeting in November 2013, sales representatives were educated on the coverage requirements of many insurance providers for Sovaldi (i.e. F-3 or F-4 patients) and the different tests used to measure patients' fibrosis scores. Specifically, FibroSure and FibroScan were discussed. The trainers instructed the sales force to ask physicians which test they used when measuring patients' fibrosis scores. Further, sales representatives were provided clinical data on how eating a fatty meal, alcohol consumption, or a strenuous workout prior to one of these tests could manipulate the fibrosis test to produce a higher F-Score result. Sales representatives were told that the increased fibrosis score could be the difference between a patient receiving treatment and not receiving treatment. During this training, it was openly discussed that as long as the patient's fibrosis score was not tested using a liver biopsy, a patient who works out or fails to fast prior to the test would produce an artificially inflated fibrosis score.

201. In addition to the aforementioned instruction, Gilead also provided sales representatives with written materials explaining how fibrosis scores could be manipulated. These

materials stated "Not for Distribution" and sales representatives were required to return these materials at the end of the training session. However, there was also information on the projector screen, and sales representatives were encouraged to take notes.

202. Relator further recalls three specific instances where the sales force received training regarding F-Scores during the Harvoni launch meeting in September 2014. First, F-Score manipulation was discussed during an expert panel. The expert panel consisted of thought leaders in the HCV medical community who were paid by Gilead to speak to the entire sales force in an assembly. According to Relator, it was Gilead's regular practice to pay experts in HCV to speak to the sales force during national sales meetings, sales trainings, and product launches. According to Relator, the purported purpose of this panel presentation was to provide the Sovaldi sales force with credible "real world" product experience that they could use in the field to influence providers to prescribe Sovaldi and Harvoni.

203. One of the panelist was Dr. Nezam Afdhal. Dr. Afdhal is a Professor of Medicine at Harvard University, and was one of the panelists who presented to the HCV sales force during the Sovaldi launch. Dr. Afdhal was introduced to the sales force as a highly respected expert whose practices are influential because of his extensive experience using Sovaldi during Phase 3 clinical trials. Further, Dr. Afdhal was the lead investigator for Gilead's Phase 3 ION-2 (Ledipasvir/Sofosbuvir) January 2013 clinical trial. [4]

204. During his presentation, Dr. Afdhal discussed the different tests used to measure a patient's F-Score (*e.g.*, AIM, FibroSure, FibroScan, etc.) and how they require a two-to-three hour fasting period prior to the test administration. Dr. Afdhal further explained that a patient's failure to properly fast could manipulate their F-Score, causing an F-2 or F-3 to report as an F-3 or F-4.

[4] Available at https://clinicaltrials.gov/ct2/show/NCT01768286.

According to Relator, Dr. Afdhal's presentation was primarily focused on Sovaldi's efficacy and safety profile, and shared the information on the F-Score tests in passing. However, this information was particularly emphasized because Dr. Afdhal is a known expert on fibrosis score tests. For example, Dr. Afdhal sponsored the clinical trial "FibroScan in Patients with Hepatitis B and C Presenting for Liver Biopsy" (July 2005), ClinicalTrials.gov identifier: NCT00125762, *available at* https://clinicaltrials.gov/ct2/show/NCT00125762.

205. Next, F-Score manipulation was discussed during the poster breakout session, which was held immediately after the Expert Panel. For this training, the sales force was divided into smaller groups that rotated through each section and were accompanied by a Gilead manager. When Relator's group visited Dr. Afdhal's section, he discussed F-Score manipulation. Although Dr. Afdhal did not explicitly say "tell providers to have their patients eat a meal prior to measuring their fibrosis score," he spent a lot of time explaining how if a patient did not fast prior to the test, the F-Score would be increased from an F-2 or F-3 to an F-3 or F-4.

206. Lastly, the F-Score manipulation was discussed during the Harvoni launch meeting's Medicare Affairs Team breakout session. For this session, the sales force was divided into teams according to their regional sales district. Relator's district consisted of sales representatives, his regional manager, and a medical affair's team member. Relator's team breakout meetings were attended by sales representatives from Washington, Oregon, Idaho, Utah, Montana, Alaska, Northern California, Northern Nebraska, and Nevada sales regions; the Northwest Regional Manager, Brad Peacock; and the Northwest Region Medical Affairs Liaison.

207. According to Relator, one of these breakout sessions was dedicated entirely to discussing F-Scores and the various tests used. The medical affairs liaison discussed the various F-Score tests (AIM score equation, FibroScan, FibroSure, etc.) and explained how these tests

measure a patient's fibrosis score on a scale from F-0 to F-4. The liaison further explained that following a fatty meal, the liver will temporarily be stiffer and because F-Score tests measure severity in terms of liver stiffness, which is why patients are required to fast for 2-3 hours before the F-Score test is administered, the F-Score will be falsely inflated if a meal is ingested before the test. The liaison specifically explained that if the patient does not fast before the F-Score test, the F-Score will be inflated, for example, an F-2 or F-3 will appear to be an F-3 or F-4.

208. Further, as discussed above, prior to the FDA's approval of Sovaldi, sales representatives were required to ask each targeted provider a series of questions. One of the questions states "What percentage of your treatment naive patients are biopsied?" As stated above, failing to fast can manipulate a patient's F-Score only if it is being measured by one of the various F-Score tests. However, failing to fast will not result in an increased F-Score if the patient's F-Score is measured by a liver biopsy. According to Relator, whether a provider tests their patients' F-Scores through liver biopsy or F-Score test is irrelevant to Gilead, and the only use of this information is for the purposes of determining whether these patients' F-Scores could be manipulated.

209. According to Relator, although Gilead never came out and explicitly said to tell providers to manipulate their patients' F-Score results by telling them not to fast, the Company provided all of the information to allow sales representatives to make this pitch to providers. And, significantly, Gilead provided a significant majority of this information right around the time that it was having trouble getting patients approved for coverage of its drugs. According to Relator, sales representatives were experiencing significant difficulties finding patients that met the coverage requirements just as Gilead provided them with information on how F-Scores could be manipulated to obtain coverage. Further, unless it was Gilead's intent that its sales representatives

would share this information with providers, it was unnecessary for Gilead to devote four separate training sessions to learning about fibrosis tests and how to manipulate the F-Score. In fact, according to Relator, Gilead spent so much time discussing the impact of eating prior to an F-Score test that it seemed as if the sales force was being trained to sell F-Score tests. Therefore, according to Relator, the only use of this information to the sales force was to provide such information to providers to help them gain insurance coverage for Sovaldi and Harvoni.

210. This sales technique was used by many sales representatives to help obtain coverage for patients who did not have a high enough fibrosis score to qualify for coverage. And Gilead senior management was either aware of such practices or were willfully ignorant to them. According to Relator, sales representatives did not feel that they were doing anything wrong by giving this instruction to physicians because it was helping patients get access to drugs that could drastically improve their condition. This was directed by Gilead, however. According to Relator, Gilead told the sales force that patients would die without this treatment, and that there should be a sense of urgency to encourage providers to treat their patients no matter what they needed to do to get the drug covered.

211. Gilead told its sales force that because Sovaldi drained payor budgets, the payors were now requiring providers to wait for patients to be very sick with fibrosis scores of F-3 – F-4 before prescribing Sovaldi. But because physicians are used to following the thought process of early detection–early treatment, it was easy for the sales force to present Sovaldi as a lifesaving treatment that all HCV patients should be prescribed immediately because if they waited for a patient's condition to worsen, they may become cirrhotic, requiring a liver transplant, and therefore become ineligible for Sovaldi. This allowed the sales force to feel comfortable telling the physicians to "try to get the patients to have a higher test score."

K. Off-Label Marketing

212. Gilead marketed Sovaldi off-label by promoting it in combination with Olysio for GT1 patients. This combination is referred to as "sim-sof." According to Relator, sim-sof was promoted by both physician speakers and sales representatives. In the speaker programs, a discussion of sim-sof would almost always come up. Further, according to Relator, sales representatives were trained on this combination. Gilead informed sales representatives that they could find clinical studies for sim-sof on the American Association for the Study of Liver Diseases' website, but advised them not to print out the studies so as to prevent a paper trail, but to direct providers to the online studies.

213. Further, Gilead instructed the sales force to focus on the "unwilling or intolerant" to interferon language in Sovaldi's FDA label to encourage physicians to prescribe this off-label treatment. Specifically, sales representatives would tell providers that any patient who was unwilling to take or intolerant to interferon could be prescribed sim–sof. Gilead openly promoted the sim–sof regimen for HCV patients, including GT1, without specifying that only genotype 2 and 3 patients were approved for an interferon free Sovaldi regimen. Sovaldi plus Ribavirin without Interferon is only approved for GT1 patients who are ineligible (*e.g.*, HIV/HCV co-infected patients) to receive interferon, not for GT1 patients who are simply interferon intolerant or unwilling. According to Relator, sales representatives would also tell providers that if they state that their patients had depression or a family history of depression in the prior authorization request, this could support the patient's case for being interferon ineligible because depression is a side effect of interferon.

L. Mitigating Safety Profile

214. According to Relator, Gilead senior management trained its HCV sales force to

overstate the safety of Sovaldi and Harvoni by making misleading claims about its side effect and safety profile. From July 2014 to October 2014, Relator claims that Gilead's sales force was instructed to tell providers that Sovaldi's and Harvoni's side effects were "better than placebo" because the discontinuation rate due to side effects was less than 1%. In fact, the sales force was instructed to say: "Patients feel better on Harvoni than they do on placebo, that's how clean the side effect profile is." Further, during Sovaldi's sales training, sales representatives were instructed to tell physicians "Sovaldi's side effects are just like being a parent: headache, insomnia, and fatigue."

215. It is important to note that Gilead's claims regarding Sovaldi's side effect profile being "better than a placebo" is also misleading because Gilead did not perform a study comparing Sovaldi's side effects to a placebos.

216. However, despite Gilead's claims, Harvoni's package insert demonstrates that the drug has greater side effects than a placebo. For example:

- Fatigue: 1% in the placebo group compared to 4% in the Harvoni + RBV 12 weeks group, and 18% in the Harvoni 24 weeks group;
- Asthenia: 23% in the placebo group compared to 36% in the Harvoni + RBV 12 weeks group, and 31% in the Harvoni 24 weeks group;
- Headaches: 16% in the placebo group compared to 13% in the Harvoni + RBV 12 weeks group, and 29% in the Harvoni 24 weeks group;
- Dyspnea: 1% in the placebo group compared to 9% in the Harvoni + RBV 12 weeks group, and 3% in the Harvoni 24 weeks group;
- Myalgia: 0% in the placebo group compared to 4% in the Harvoni + RBV 12 weeks group, and 9% in the Harvoni 24 weeks group;
- Irritability: 1% in the placebo group compared to 7% in the Harvoni + RBV 12 weeks group, and 8% in the Harvoni 24 weeks group; and
- Dizziness: 0% in the placebo group compared to 1% in the Harvoni + RBV 12 weeks group, and 5% in the Harvoni 24 weeks group.

217. The claims that Sovaldi's side effects are *"better than placebo"* and *"like being a parent"* are both false and misleading because Section 6, Adverse Reactions, Table 3 (see below)

of the FDA approved Sovaldi Package Insert ("PI") states that in all clinical trials combined, the treatment regimens that contain Sovaldi (highlighted in the table below) in fact have more side effects than placebo.

Treatment-Emergent Adverse Events (All Grades) Reported in ≥ 15% of Subjects in Any Treatment Arm					
	Interferon-free Regimens			Interferon-containing Regimens	
	PLACEBO 12 weeks	SOVALDI + RBV[a] 12 weeks	SOVALDI + RBV[a] 24 weeks	Peg-IFN alfa + RBV[b] 24 weeks	SOVALDI + Peg IFN alfa + RBV[b] 12 weeks
	N=71	N=650	N=250	N=243	N=327
Fatigue	24%	38%	30%	55%	59%
Headache	20%	24%	30%	44%	36%
Insomnia	4%	15%	16%	29%	25%
Pruritus	8%	11%	27%	17%	17%
Anemia	0%	10%	6%	12%	21%
Asthenia	3%	6%	21%	3%	5%
Rash	8%	8%	9%	18%	18%
Decreased Appetite	10%	6%	6%	18%	18%
Influenza like Illness	3%	3%	6%	18%	16%
Pyrexia	0%	4%	4%	14%	18%
Diarrhea	6%	9%	12%	17%	12%
Neutropenia	0%	<1%	<1%	12%	17%
Myalgia	0%	6%	9%	16%	14%
Irritability	1%	10%	10%	16%	13%

a. Subjects received weight-based ribavirin (1000 mg per day if weighing < 75 kg or 1200 mg per day if weighing ≥75 kg).
b. Subjects received 800 mg ribavirin per day regardless of weight.
(Highlight added)

Sovaldi Package Insert, Section 6, Adverse Reactions, 6.1 Adverse Reactions from Clinical Trials Experience.

218. Further, Section 6, Adverse Reactions, of the Sovaldi PI also illustrates that in all clinical trials combined, the treatment regimens that contain Sovaldi (highlighted in the table below) in fact have more of a negative impact on red and white blood cell counts than a placebo, thus increasing the risk for Anemia and Neutropenia.

Percentage of Subjects Reporting Selected Hematological Parameters						
		Interferon-FREE Regimens			Interferon-containing Regimens	
Hematological Parameters		PLACEBO 12 weeks	SOVALDI + RBV[a] 12 weeks	SOVALDI + RBV[a] 24 weeks	Peg-IFN alfa + RBV[b] 24 weeks	SOVALDI + Peg IFN alfa + RBV[a] 12 weeks
		N=71	N=650	N=250	N=243	N=327
Hemoglobin (g/dL)	< 10	0%	8%	6%	14%	23%
	< 8.5	0%	1%	<1%	2%	2%
Neutrophils (x109/L)	≥0.5 - < 0.75	1%	<1%	0%	12%	15%
	< 0.5	0%	<1%	0%	2%	5%
Platelets (x109 /L)	≥25 - < 50	3%	<1%	1%	7%	<1%
	< 25	0%	0%	0%	0%	0%

a. Subjects received weight-based ribavirin (1000 mg per day if weighing < 75 kg or 1200 mg per day if weighing ≥75 kg).
b. Subjects received 800 mg ribavirin per day regardless of weight.
(Highlight added)

M. Premier Pays Pharmaceutical Sales Representatives for Prescriptions in Violation of the AKS

219. According to Relator, Premier is paying pharmaceutical sales representatives to direct HCV medication prescriptions to its pharmacy in violation of the AKS. Specifically, Premier is paying sales representatives from at least Gilead, Abbvie, and Boehringer Ingelheim to send HCV prescriptions to its pharmacy. Upon information and belief, Premier is also paying sales representatives from other pharmaceutical companies to direct HCV prescriptions to its pharmacy. Internally at Premier, they called this "moonlighting" because the sales representatives worked full time for the pharmaceutical company, but they also "moonlight" for Premier by directing prescriptions to its pharmacy in exchange for kickbacks.

220. According to Relator, S.M., who is now Premier's National Director of Sales for HCV drugs, and R.P., Premier's VP of Sales, enter into agreements with and pay pharmaceutical sales representatives, on behalf of Premier, to send prescriptions to Premier. Although both S.M. and R.P. are management, they both still have their own sales territories.

221. Relator first heard that Premier was paying sales representatives to send it prescriptions shortly before the Harvoni launch. Specifically, Relator attended a meeting where several Sovaldi sales representatives were discussing that Premier representatives had approached them and offered to pay for each prescription they directed to the pharmacy.

222. As mentioned above, Relator initially worked primarily with BioPlus, however, Premier was one of the three specialty pharmacies Relator worked with. Relator then started directing most of his Sovaldi prescriptions to Premier. The Premier representative Relator worked with was S.M. Relator previously worked with S.M. in the same sales region promoting Pagasys

for Genentech in neighboring territories, with Relator in Oregon and S.M in Northern California.

223. S.M. promoted HCV injection, Pegasys, from January 2008 to January 2012, and oral medication, Incivek, for Vertex Pharmaceuticals from August 2010 to November 2013 in New York. Because of his extensive relationships with health care professionals who prescribe HCV medications, S.M. began "moonlighting" for Premier, being paid a commission for any HCV medication prescriptions he steered to Premier. On October 29, 2013, Vertex laid off its HCV sales force as part of its plan to stop manufacturing Incivek. From November 2013 to June 2014, and while Relator was promoting Sovaldi for Gilead, S.M. resided in Berkeley, California and was a full time 1099 HCV sales representative for Premier in the Northwest region being paid large commissions in exchange for securing prescriptions.

224. R.P. promoted HBV medications for Gilead from 2004 to 2010 and HCV medication, Incivek, for Vertex Pharmaceuticals from November 2010 to October 2013 in California. Because of his extensive relationship with HCV prescribers, R.P. began moonlighting for Premier, being paid commission for each prescription he directed to its specialty pharmacy. In October 2013, Vertex also laid off R.P. and he immediately began working full time as a 1099 Premier HCV sales representative in California. In November 2013, his first month at Premier, R.P. successfully directed 53 HCV prescriptions to Premier and received thousands of dollars in commission payments in return. According to Relator, Premier launched its HCV Franchise when R.P and S.M. met with Premier's owner and CEO, S.S., and explained that they all could make a lot of money by running a designated HCV specialty pharmacy franchise at Premier, targeting certain high value HCV drugs, like Sovaldi.

225. At the time, although Premier was already paying kickbacks to moonlighting pharmaceutical sales representatives from various companies who directed HCV prescriptions to

its pharmacy, S.M. and R.P were the only full time 1099 Premier HCV sales representatives. According to Relator, to grow the HCV franchise, S.M. and R.P. were responsible for soliciting pharmaceutical sales representatives to direct HCV prescriptions to Premier by offering them kickbacks in the form of cash payments. S.M. and R.P. recruited pharmaceutical sales representatives to serve as moonlighters across the country in exchange for a cut of their commissions. For example, in June 2014, S.M. recruited Relator, employed by Gilead, to moonlight for Premier by directing Sovaldi prescriptions to its specialty pharmacy in exchange for kickbacks. Relator received payments by personal check from S.M. for amounts over $1,000 from June 2014 to September 2014 before becoming a 1099 Premier HCV Regional Sales Director in the Pacific Northwest in October 2014.

226. J.E., who promoted Incivek with S.M. and R.P. at Vertex from 2011 to 2013 in the Idaho, Montana, and Wyoming territories, also moonlighted for Premier. While employed at Abbvie for the pre-launch promotion of Viekira Pak, from December 2013 to November 2014, J.E. was recruited by S.M. and R.P. to leverage his strong relationships with HCV prescribers in the Upper Midwest region to direct HCV prescriptions to Premier. In exchange, J.E. received kickback payments from S.M. and R.P. of $800 to $1,000 per prescription for any HCV medications he directed to Premier until October 2014 and $220 per fill thereafter. Shortly after Relator was hired, in November 2014, J.E. became a 1099 Premier HCV Regional Sales Director responsible for the Idaho, Montana, Wyoming, Utah, North Dakota, and South Dakota territories, and continued receiving $220 per fill for any HCV prescription he referred to Premier.

227. Prior to October and November 2014, when Relator and J.E. became 1099 employees, Premier relied solely on an extensive network of moonlighting pharmaceutical sales representatives recruited by R.P. and S.M. for HCV prescriptions. To conceal the kickback

payments, R.P. created Happy Home Marketing, located at 444 North Street, Healdsburg, CA 95448. Each month, Premier paid R.P., through Happy Home Marketing, the agreed upon internal commission rate for all HCV prescriptions it received each month. R.P. then paid each moonlighter their cut either in cash or by personal check for the total prescriptions they directed to Premier each month.

228. According to Relator, initially S.S. was okay with paying pharmaceutical sales representatives for prescriptions, but as sales started increasing he became concerned, which prompted his directive for Premier to hire its own sales force. R.P. told Relator that Premier's owner, S.S., hired him to help build Premier's HCV sales force. That is, S.S. wanted Relator to help build and legitimize Premier's sales force so it could secure its own HCV prescriptions, instead of relying primarily on paying moonlighting pharmaceutical representatives for prescriptions.

229. Specifically, S.S. wanted Premier to hire a sales force of W-2 and 1099 employees in order to give the appearance that it had a legitimate sales force and to conceal the cash payments being made under the table. According to Relator, S.S. tried to keep these payments covert and at arm's length by instructing that all kickback payment be made through Happy Home Marketing. Therefore, beginning in October 2014, with Relator, and November 2014, with J.E., Premier converted the high volume moonlighters, who were willing to leave their pharmaceutical employers, to 1099 and W-2 Premier HCV sales representatives, with the immediate goal of having coverage in all fifty states. By January 2015, Premier employed six full time and eleven part-time HCV sales representatives who either previously moonlighted for Premier, were spouses of Premier employees, or former employees of competitor specialty pharmacies.

230. Premier paid all sales representatives, including those working for pharmaceutical

companies, through Happy Home Marketing. Full time or part time Premier sales representatives were paid their commissions earned each month by 1099 or W-2 payroll through Happy Home Marketing. Happy Home Marketing was also reimbursed by Premier each month for payments made in cash or by personal check to moonlighting pharmaceutical representatives directing prescriptions to Premier. In addition, full time Premier sales representatives were allowed a $500 per month marketing expense account, which was later increased to $1,500 per month, were reimbursed for all Premier related food and travel, and were reimbursed for gifts purchased for HCV prescribers and their staff, through Happy Home Marketing. For example, Relator was reimbursed for gift cards, See's candy, floral arrangements and miscellaneous gifts, which ranged from $5 in value to over $100 for special occasions or holidays. In 2016, Relator was reimbursed over $5,000 for See's candies gifted to providers' offices.

231. All Premier sales representatives were compensated solely on commission and many of the full-time Premier sales representatives were given company cars. According to Relator, W-2, full-time employees were given a Prius, and 1099 employees were provided a monthly allowance of $500 for car expenses. Further, all employees were provided a $150 monthly allowance for cell phone expenses. These expenses were also paid through Happy Home Marketing. For example, while employed as a full time 1099 contractor at Premier, Relator received a $1,500 marketing expense allowance, $500 monthly car allowance, a $150 monthly cell phone allowance, unlimited expense reimbursement for food and travel. And Relator received his commission payments through Happy Home Marketing.

232. Premier also operated as a glorified pyramid scheme. Specifically, high volume moonlighters and Premier HCV sales representatives would recruit other pharmaceutical sales representatives to direct prescriptions to Premier, in exchange for a cut of their commissions, paid

via cash or by personal check. For example, S.M. recruited Relator to moonlight for Premier in June 2014, while Relator was employed at Gilead. At the time that he recruited Relator, in 2014, S.M. left Premier and joined Bristol Myers Squibb for the launch of its HCV medication, Daklinza. However, S.M. continued moonlighting for Premier while promoting Daklinza, being paid commissions for HCV medications he directed to Premier. Simultaneously, from June 2014 to September 2014, while moonlighting, S.M. was also paying Relator to moonlight for Premier under him.

233. According to Relator, in June 2014, he was experiencing family issues and subsequent financial difficulties. S.M., who was aware of Relator's financial difficulties, started sending him checks, every month, in amounts upwards of $1,000, from S.M.'s personal checking account as a sign of gratitude for the Sovaldi prescriptions Relator was directing to Premier. S.M. told him that he was aware of Relator's financial difficulties and the checks were just to "help him through this period." Relator later became aware that S.M. has also paid other moonlighting pharmaceutical sales representatives to direct prescriptions to Premier and even witnessed him pay cash to a pharmaceutical sales representative in exchange for prescriptions. Further, Relator's Premier payout record from June 2014 to October 2014, emailed to him on November 8, 2014, from R.P., illustrates that he was being paid for prescriptions that he directed to Premier in June, July, August, and September 2014, while he was working for Gilead and promoting Sovaldi.

PHYSICIAN	DATE RECEIVED	STATUS	DRUG	PAYOUT	
BORLAND	8-Aug	D	S	220	TOBY
BUTANI	28-Oct	D	H	220	TOBY
CHOW	30-Sep	D	S	800	TOBY
CHOW	7-Oct	D	S	800	TOBY
DAVIGNON	23-Oct	D	S	220	TOBY
DE LEE	24-Sep	D	S	800	TOBY
DE LEE	29-Sep	D	S	800	TOBY
FAWCETT	15-Aug	D	S	220	TOBY
LUTZ	23-Oct	D	H	220	TOBY
MYERS	24-Jun	D	S	220	TOBY
NADER	20-Oct	D	H	220	TOBY
NADER	30-Oct	D	H	220	TOBY
TRAN	24-Oct	D	S	220	TOBY
WEED	14-Oct	D	S	220	TOBY
WEED	20-Aug	D	S	220	TOBY
				$5,620	

234. As shown above, even though Relator worked at Gilead as a Sovaldi sales representative until October 2014, Premier was tracking and paying him kickbacks for Sovaldi prescriptions he directed to Premier as far back as June 2014.

235. Upon starting with Premier, Relator learned that S.M. and R.P. had been paying sales representatives across the nation from Gilead, Abbvie, Boehringer Ingelheim, and other pharmaceutical companies in exchange for them directing prescriptions to Premier. According to Relator, most pharmaceutical representatives moonlighting for Premier were paid by cash in order to avoid a paper trail and conflicts with their full-time employer.

236. For moonlighters that directed a high volume of prescriptions to the pharmacy, the Premier sales representative who recruited the moonlighter would pay them in cash or by check from their personal checking account and were reimbursed by Happy Home Marketing. For lower volume moonlighters, the Premier sales representative who recruited them would give them a cut of the commission they received from Premier. According to Relator, these payments were normally made in cash.

237. For example, in October 2014, when Premier hired Relator, he was assigned the Oregon, Washington, and Alaska territories. Relator formed his own consulting company through

which he hired two 1099 moonlighters to assist in securing prescriptions in those territories. Relator paid these moonlighting pharmaceutical sales representatives through his consulting company, and was reimbursed by Happy Home Marketing. The moonlighters Relator hired were not officially working for Premier, and the prescriptions they secured were not tracked on the Weekly Scoreboard (discussed below), as the Weekly Scoreboard only tracked prescriptions secured from legitimate Premier sales representatives. According to Relator, prescriptions secured by moonlighters were tracked separately.

238. According to Relator, S.M. paid several of his moonlighters in cash or by personal check. Relator is also aware that there were numerous other moonlighters working under R.P. who were paid off the books by Happy Home Marketing. By allowing their sales representatives and high volume moonlighters to recruit other pharmaceutical sales representatives to serve as moonlighters and direct prescriptions to its pharmacy, Premier knowingly expanded the network of their nationwide scheme to direct HCV prescriptions to their pharmacy in exchange for kickback payments.

239. Initially the commission that moonlighters were paid was $800 or $1,000 per prescription, however, in October 2014, Premier began paying $220 for each prescription fill instead. Premier made this change because after the initial fill, some payers require the refills be transferred to their contracted specialty pharmacy. HCV medications are normally dispensed in a 30-day supply, with refills. Thus, for a 12-week regimen, there are three prescription fills, which would result in a $660 payment to the sales representative. For a 24-week regimen, there are six prescription fills, which would result in a $1,320 payment to the sales representative. A low volume moonlighter may receive a $100 cut of the $220 per fill commission the sales representative received.

240. According to Relator, even after he started at Premier, it still continued to pay pharmaceutical representatives, including Sovaldi and Harvoni sales representatives, to send prescriptions to its pharmacy.

241. Relator is aware that the payments to sales representatives did not stop after he was hired because he personally witnessed Premier pay a Boehringer Ingelheim sales representative for directing prescriptions to its pharmacy. According to Relator, the sales representative who received the cash payment had previously worked with S.M. and R.P. at a different company. According to Relator, this sales representative had relationships with many HCV providers and was therefore able to direct prescriptions to Premier.

242. Relator was also aware that J.E. was being paid as a moonlighter for directing HCV medication prescriptions to Premier while he was employed at Abbvie, promoting Viekira Pak. As stated above, after J.E. left Abbvie, in November 2014, Premier attempted to legitimize J.E.'s role at the Company by paying him as a 1099 employee rather than under the table cash payments. According to Relator, through its glorified pyramid scheme described above, Premier continues to pay various pharmaceutical sales representatives, from different companies, throughout the country in exchange for sending HCV prescriptions to Premier.

243. G.B., Premier's Vice President of Oncology and Compounding Franchise, informed Relator that its kickback scheme for HCV medications was modeled after the same exact scheme Premier used to secure prescriptions for its Oncology and Compounding department. G.B. further informed Relator that Premier paid a combined $3,000 commission for wound and scar cream prescriptions which are prescribed together. In fact, G.B. told Relator that he, S.M., R.P., and R.P.'s wife all had physicians prescribe them scar or wound cream, which was filled by Premier, so they could receive the $3,000 commission. Further, Premier sales representatives

would solicit pharmaceutical sales representatives to direct compound prescriptions to Premier and in return Premier would give a share of the commission payment to the pharmaceutical representative for directing prescriptions to Premier. G.B. explained that Premier targeted Tricare patients because they had a high potential use for compounded wound and scar creams and due to Tricare's favorable coverage of compounded medications. G.B. further explained that Premier also targeted Tricare patients, due to Tricare's favorable coverage, for compounded multi-vitamin prescriptions and that Premier paid $500 commission, per fill, for compounded multi-vitamins.

244. Currently, Premier has approximately 15 HCV sales representatives, a countless number of moonlighting pharmaceutical representatives working either under the table for Happy Home Marketing (R.P.), S.M, or Premier HCV sales representatives, two internal pharmacists (K.B. and T.V.) solely focused on HCV drugs, and an entire internal team of dedicated HCV Concierge representatives who provide white glove service to health care providers that prescribe HCV drugs. Further, Relator states that Premier has about $30,000,000 per month in sales from HCV drugs alone.

245. Each week, Premier provided its sales representatives an excel spreadsheet containing "Weekly Scoreboards," which lists each Premier sales representative and the total number of new HCV prescription they had for that week. The Weekly Scoreboard contained the new HCV prescriptions received by Premier for both Premier's full-time sales employees (i.e., W-2 or 1099), who are identified as "FT" on the spreadsheet, as well as part-time employees (i.e., W-2 or 1099), who are identified as "PT."

246. For example, below are pictures from the Weekly Scoreboard for the weeks of February 2, 2015 and March 23, 2015:

February 2, 2015:

REP	Rx's	
TT	17	FT
LP	16	PT
JE	12	FT
AH	9	PT
KH	8	PT
VT	7	PT
DG	4	PT
MD	4	PT
NT	3	FT
SG	2	FT
BH	2	PT
JL	1	PT
LH	1	FT
AA	0	FT
KN	0	PT
MS	0	PT
JR	0	PT
Total Rx's:	**107**	
Harvoni	**78**	
Sovaldi	**18**	
Viekira	**11**	
Total New Docs:	**3**	
Total for FEB:	**107**	

March 23, 2015:

REP	Rx's	
TT	19	FT
JE	15	FT
VT	9	PT
SG	8	FT
NT	8	FT
LP	5	PT
LH	5	FT
AH	4	PT
MD	2	PT
DG	2	PT
BH	1	PT
KH	1	PT
JL	1	PT
KN	1	PT
AA	0	FT
JR	0	PT
Total Rx's:	**104**	
Harvoni	**79**	
Sovaldi	**15**	
Viekira	**10**	
Total New Docs:	**5**	
Total for MAR:	**453**	

247. The Weekly Scoreboard tracks the total number of new HCV prescription each sales representative secured for the pharmacy each week. The "Total Rx's" amount is the total number of prescriptions received by Premier for Sovaldi, Harvoni, and Viekira Pak. The "Total

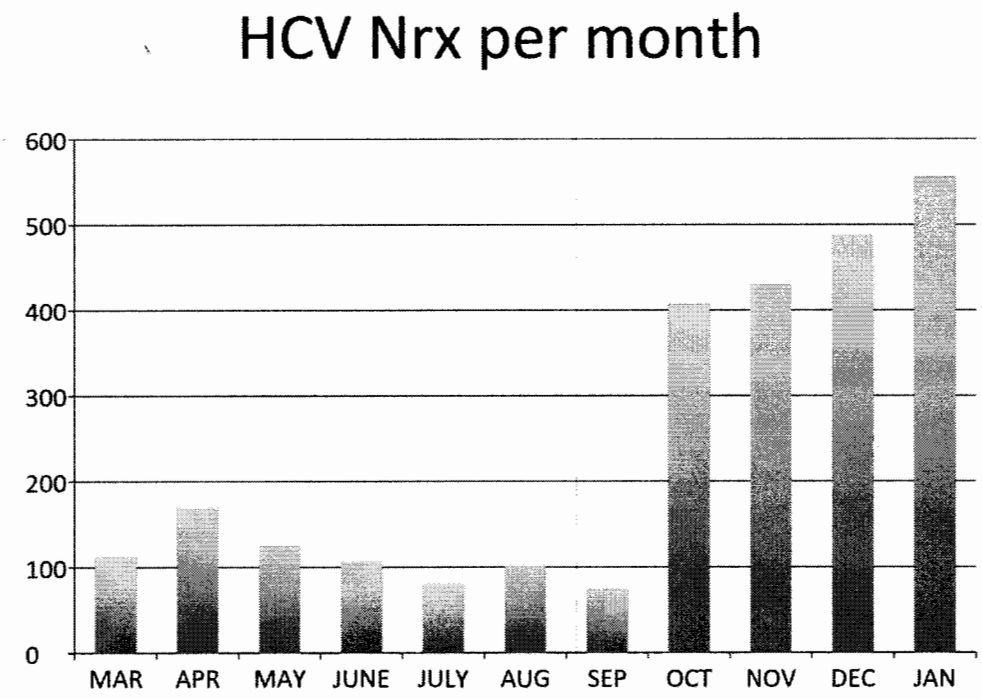
New Docs" represents the total number of physicians who were using Premier for the first time. The "Total for Mar" and "Feb" figure is the total number of HCV prescriptions filled by the pharmacy so far that month. Thus, in the first week in February, the "Total Rx's" and "Total for Feb" figures are the same because these numbers are from the first week in February. The figures for March, however, show "Total Rx's" at 104, and "Total for Mar" at 453 because at the time the spreadsheet was created, Premier had filled 453 prescriptions for Sovaldi, Harvoni, and Viekira Pak, thus far in March.

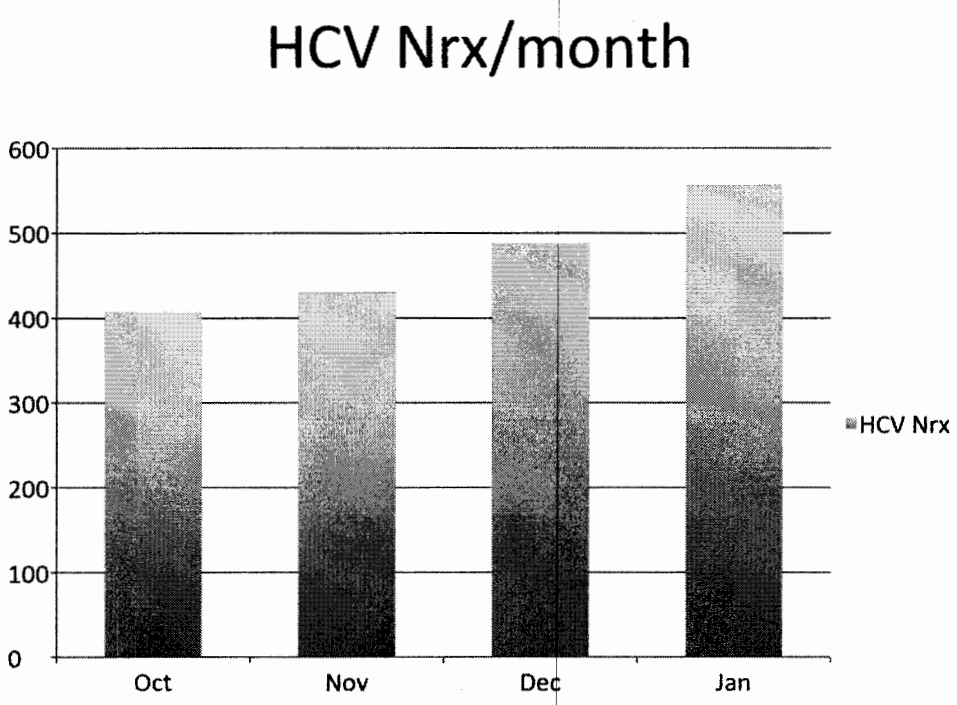
248. Further, the sales representatives listed on the Weekly Scoreboards above are legitimate sales representatives, meaning that they are employed either full-time or part-time by Premier as either a 1099 or W-2 employees. Therefore, the Weekly Scoreboards did not include prescriptions secured through moonlighting sales representatives. Prescriptions secured by moonlighters were tracked separately.

249. Premier's scheme to pay pharmaceutical sales representatives to direct prescriptions to its pharmacy was very successful. This is demonstrated in a February 2, 2015 email from R.P. to the Premier sales force. In the email, R.P. announces that Premier had "Another solid week and only 2 away from our record of 152. We not only reached 500 for the month, we crushed it! 556 is the final numbers with a total of 26 new prescribers. Again, really great work!" The email concluded by stating:

> I think what's really great is that if you look at the scoreboard over the weeks, you'll notice that the volume is starting to come in from more and more people. The overall growth has been phenomenal. In addition to the Weekly Scoreboard I've attached a couple of slides as well that will help illustrate where we were and how far we've come since our expansion for launch in October. I hope that as the volume comes in, more and more of you are seeing the fruits of your labor. As you'll see in the slides, we're definitely headed in the right direction. With all the contracting that has been happening, hopefully we'll all see the growth across the board.

250. Further, as referenced in the above email, R.P. attached two PowerPoint slides to the email demonstrating Premier's growth in HCV medication prescriptions since their "expansion for launch" in October 2014. The two slides are as follows:





251. The slides above demonstrate that from March until September 2014, Premier averaged approximately 100 HCV prescriptions per month from their network of moonlighting sales representatives. In October 2014, when Premier started to expand their sales force and its network of moonlighters, HCV prescriptions immediately grew to over 400 in October 2014; over 425 in November 2014; over 475 in December 2014; and over 550 in January 2015.

N. Premier Provides Practices with Free Services in Exchange for Prescriptions in Violation of the AKS

252. Premier provides practices with free services in the form of FibroScan testing in exchange for prescriptions, in violation of the AKS.

253. According to Relator, on October 10, 2016, Premier leased a $200,000 FibroScan System from Echosens for $4,600 per month in order to provide HCPs with an in-office FibroScan testing machine for their HCV patients. As discussed in more detail below, this offer was intended

to, and did in fact, induce prescriptions of HCV medications. This conduct violates the AKS, it also violates the FCA.

254. Due to the high cost of the FibroScan system, most practices do not have one in their office, and therefore their patients must travel to a location that does have one, normally academic hospitals, to test their F-Score. For many patients, they must travel several hours to an academic hospital so they can receive a FibroScan test. Payers require fibrosis scores as part of the prior authorization process for HCV medications and several payers, including Medicare and Medicaid, consider the FibroScan test as the new standard of care.

255. Premier, knowing that being able to perform FibroScan tests in their offices was of great value to providers, leased a FibroScan machine from Echosens and offered to hold FibroScan "clinics" at the provider's office where their patients could receive a FibroScan test. According to Relator, approximately 12-15 patients would attend Premier's FibroScan Clinics.

256. The FibroScan Clinics were hosted by Premier and Q.D., an Echosens sales representative, and occasionally Echosens regional manager, C.M. Further, the physician whose practice was receiving the clinic did not spend any time with patients during the clinic. However, the practice's medical assistants would participate in the clinics. Therefore, prior to doing a clinic, Echosens and Premier trained three medical assistants from each practice and subsequently certified them on the FibroScan system. Premier would train and certify the practice's medical assistants in both fibrosis testing and NASH testing (non-alcoholic steatohepatitis or fatty liver disease), which could also be performed on a FibroScan.[5] According to Relator, Premier told its sales representatives to entice practices by telling them that after their medical assistants were certified, they could borrow Premier's FibroScan system to use on their own patients.

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[5] NASH is a chronic condition that effects ten-to-fifteen times as many patients as HCV.

257. In fact, a Premier FibroScan Clinic pilot program PowerPoint presentation was prepared for the New York region, and discusses the revenue potential for Premier from the FibroScan Clinics. The presentation states, in part, that:

> The FibroScan 530 Compact will drive this growth via: Allowing for the triage and qualification of NAFLD and NASH patients in anticipation of NASH molecule. $30,000-$50,000 per treatment; $30-36 BIL market.

258. This training and certification, alone, was very valuable to providers. Echosens normally provides free training and certification to three employees who work for a practice that purchased a FibroScan system, and then charges $1,800 for each additional training session they perform. However, due to Premier's FibroScan Clinics proposal, Echosens, in their contract with Premier, agreed to train and certify one Premier employee, and provide training and certification to three employees at ten practices that Premier selected. Premier's FibroScan Clinics were valuable to Echosens because they allowed the company the opportunity to showcase the FibroScan 530C machine to many high volume HCV providers. Pursuant to the contract between Echosense and Premier, after Echosens had performed training and certification at the ten practices, Echosens would provide training and certification to additional practices for $1,800 each. According to Relator, Echosens agreed to include ten training sessions with the purchase of the FibroScan system because they viewed Premier's FibroScan Clinics as an opportunity to promote the FibroScan 530C system to health care providers.

259. Thus, as there is a value attached to the FibroScan training and certification, providing such training and certification to practices for free constitutes remuneration. And because this remuneration was provided with the intent to, and did, in fact, induce prescriptions, Premier has violated the AKS.

260. Further, upon information and belief, Premier exceeded the free training at ten

practices and subsequently paid the $1,800 to train and certify practices' staff, in violation of the AKS. According to Relator, he personally organized training and certification courses for four practices. However, when he left Premier, there were at least ten additional practices that Premier was preparing to perform FibroScan Clinics at. Specifically, Premier had already discussed with and was in the process of arrangement for FibroScan Clinics in the following practices: (1) Northwest Gastroenterology Clinic, LLC. 1130 NW 22nd Avenue, Suite 410, Portland, OR 97210; (2) Dr. Justin Goodman, Gastroenterologist at The Polyclinic, 1145 Broadway, Seattle, WA 98122; (3) Southlake Clinic Gastroenterology, 4011 Talbot Road Street, Fifth Floor, Renton, WA 98055; (4) Infections Limited, 1624 South I Street, Suite 305 & 405, Tacoma, WA 98405; (5) Digestive Disease and Endoscopy Center, 3261 NW Mount Vintage Way, Suite 221, Silverdale, WA 98383; (6) Clearwater Gastroenterology, 2517 17th Street, Suite B, Lewiston, ID 83501; (7) Idaho Gastroenterology Associates, 425 West Bannock Street, Boise, ID 83702; (8) Digestive Health Clinic, 6259 West Emerald Street, Boise, ID 83704; (9) Saint Luke's Gastroenterology Clinic, 775 Pole Line Rd West, Suite 203, Twin Falls, ID 83303; and (10) Grand Teton Gastroenterology, 2770 Cortez Ave, Idaho Falls, ID 83404.

261. Premier's FibroScan Clinics were also valuable to providers because they did not have to inconvenience their patients by making them travel hours away to receive a FibroScan test. However, Premier's FibroScan Clinics also allowed providers to bill for services that they otherwise could not have billed for and that they did not perform.

262. FibroScan tests are billed under CPT code 91200. Reimbursement under 91200 is $39.12. When the FibroScan test is administered, providers are permitted to bill under 91200 or under an E/M code, but not both. According to Relator, all providers who Premier conducted a FibroScan Clinic for elected to bill for the E/M visit for each patient that received a FibroScan test,

under either 99214 or 99215, which was reimbursed at over $100. Thus, by providing the FibroScan Clinics, Premier provided practices with the ability to bill for a procedure they would not have otherwise been able to bill for. Further, as discussed above, the treating physician did not participate in the FibroScan Clinics, which is required to bill for an E/M visit. Rather, Premier and Echosens staff conducted the clinics, with the assistance of the practice's medical assistants. Therefore, Premier's FibroScan Clinics were providing practices with the ability to bill for a service they did not perform or have any involvement with.

263. Premier sales representatives told practices that they would receive approximately $100 in reimbursement for each patient tested during a FibroScan Clinic. To demonstrate this, Premier provided its sales representatives with a marketing piece showing the different E/M CPT codes that could be billed in connection with performing a FibroScan test on a patient. As shown below, by billing at the two highest E/M codes – 99214 and 99215 – practices would receive at least $100 in reimbursement for each patient tested. And, according to Relator, most practices would bill an E/M office visit under 99214 or 99215 for patients who received a FibroScan test. The marketing piece is as follows:

Physician office average Medicare $39.12

Physician office average private pay $50.86

ICD –attached

Office Visit

Associated Office Visits	CPT	RVU	CMS Pay
No Associated Office Visit			$0.00
Office Visit (10 min)	99212	1.23	$44.14
Office Visit (15 min)	99213	2.06	$73.93
Office Visit (25 min)	99214	3.03	$108.74
Office Visit (40 min)	99215	4.08	$146.43

264. Premier realized that its arrangement – providing FibroScan Clinics to providers in exchange for HCV medication prescriptions – would violate the AKS, and therefore devised a scheme to make this arrangement appear legitimate. Specifically, S.S., the owner of Premier, created a sham "lease agreement" for each provider to sign before conducting the FibroScan Clinic. The lease agreement stated that Premier was an independent contractor to the practice and the practice would pay Premier a $10 fee for each FibroScan test they performed. However, based on Relator's experience at Premier, he believes that the lease agreements were just for show, and Premier never actually billed or collected this fee from providers. And, even if Premier did collect the $10 fee, this conduct would still violate the AKS.

265. Premier created a document to send to providers announcing their partnership with Echosens and offering providers the opportunity to participate in the FibroScan pilot program, which consisted mainly of FibroScan operator training and clinics. The title of the document is "Partnership Announcement and Pilot-Site Recruitment Tool." This document was sent to, among others, Salem Gastro; Gastroenterology Consultants, P.C.; Eugene Gastroenterology Consultants; and Internal Medicare Associates, LLC. The document states, in part, the following:

> Providing unprecedented access to care:
>
> - Our In-Office FibroScan Clinic allows patients access to FibroScan, which is increasingly being **required** by government and commercial payors as the standard-of-care in fibrosis-scoring, a primary requirement of the prior-authorization process for HCV and NASH treatment. In most cases, the nearest available FibroScan site is a 4-6 hr round-trip drive, which is not an option and therefore eliminates a majority of would-be candidates for treatment.
>
> - Our In-Office FibroScan Clinic not only provides a significant increase in access-to-care for patients, **it also provides an additional revenue stream for practices who treat and mange liver disease.** Only a nominal fee of $10 per patient is invoiced in order to remain in compliance with the Anti-Kickback Statute. **However, reimbursement for conducting and reading the FibroScan, along with a level 3 office visit, makes In-Office FibroScan Clinic a profitable endeavor as well.**

- On-site training and certification of up to 3 medical professionals, per clinic site, is provided at no cost to you. Additionally, a FibroScan Consultant is present during all patient-scans to provide additional support during In-Office FibroScan Clinic.

(emphasis added).

266. First, this document informs providers that insurance providers are increasingly requiring providers to have a patient's fibrosis-score tested before they can treat the patient for HCV or NASH. Thus, many providers must have their patients undergo a FibroScan test in order to treat their patients for HCV or NASH. And, without the test, they will be unable to bill for treating HCV or NASH. In other words, many providers need this test performed in order to treat patients and bill their insurers.

267. The announcement goes on to state that in many cases, the closest FibroScan system is miles away, and as a result many patients do not get the test, and therefore the provider cannot treat their HCV. Thus, the announcement points to an obstacle to practice's ability to treat patients and bill their providers.

268. The announcement also offers to train and certify up to three medical professionals per practice, at no cost to the practice.

269. Most significantly, the announcement states that only a "nominal fee of $10 per patient" is required in order to remain compliant under the AKS. This statement demonstrates that Premier was aware that the FibroScan Clinics, training and certification are valuable to providers.

270. Even if Premier did collect the $10 per patient fee (which it is believed to have not), this would not bring Premier's practice into compliance with the AKS, in part, because Premier, by its own admission, is providing referral sources with a "profitable endeavor," even if it did collect the $10, in exchange for providers sending prescriptions to its pharmacy. Therefore,

Premier is clearly providing remuneration in exchange for referrals.

271. Lastly, the announcement states "reimbursement for conducting and reading the FibroScan, along with a level 3 office visit, makes In-Office FibroScan Clinic a profitable endeavor as well." Premier's statement that the billing associated with its FibroScan Clinics makes this arrangement "a profitable endeavor **as well**" is a recognition that, even if practices could not bill for the FibroScan services, the FibroScan Clinics are profitable to practices because they allow patients to fulfill the prerequisites for treating HCV and NASH. If the Fibrosis score requirement is not met, insurance providers will not pay, and providers cannot bill for, treatment of HCV and NASH.

272. However, the announcement goes further and explicitly states that for each patient who is tested during the FibroScan Clinics, practices can bill for "conducting and reading the FibroScan, along with a level 3 office visit." According to Relator, and as detailed in the announcement referenced above, initially, Premier told practices to bill the FibroScan test (i.e. technical and professional component) under CPT code 91200 for performing the scan and review, as well as CPT code 99213, an office visit. However, Premier soon found out that insurance providers would not reimburse for both 91200 and an E/M code for the same patient for the same visit. Therefore, according to Relator, practices would typically bill the FibroScan test under either 99214 or 99215.

273. According to Relator, Premier targeted high volume HCV providers for the FibroScan Clinics, as these were the practices in the best position to send Premier large quantities of HCV medication prescriptions. Further, prior to conducting the FibroScan Clinics, the Premier sales representative would secure a commitment from the health care provider to use Premier as their specialty pharmacy of choice for all specialty medications. And, significantly, Premier only

held FibroScan Clinics at practices that agreed to send them all of their HCV prescriptions. Indeed, Premier only held FibroScan Clinics at practices that agreed to use Premier as its "exclusive specialty pharmacy," and send all of its HCV prescriptions to them.

274. Relator, as a Premier sales representative, scheduled six FibroScan Clinics, each attended by approximately 10-15 patients, at high volume HCV practices in the Pacific Northwest. Specifically, Relator conducted two FibroScan Clinics at Salem Gastroenterology ("Salem Gastro"), 875 Oak St. S.E., Suite C3010, Salem, OR 97301; two FibroScan Clinics at Gastroenterology Consultants, P.C., 2860 Creekside Circle, Medford, OR, 97504; one FibroScan Clinic at Eugene Gastroenterology, 3355 Riverbend Drive, Suite 500, Springfield, OR 97477; and scheduled one FibroScan Clinic at Anchorage Internal Medicine, 2841 DeBarr Road, Suite 50, Anchorage, AK 99508, that took place shortly after Relator left Premier.

275. For example, on October 21, 2016, Premier conducted a FibroScan training session for three of Medford Gastroenterology Consultants' medical assistances, during which six to eight patients were tested. On November 29, 2016, Premier conducted a FibroScan Clinic at Medford Gastroenterology Consultants, where ten patients were tested. On January 24, 2017, Premier conducted a second FibroScan Clinic at Medford Gastroenterology Consultants, where fourteen patients were tested.

276. On December 5, 2016, Premier conducted a FibroScan training session for three of Salem Gastro's medical assistants, during which nine patients were tested. On January 26, 2017, Premier conducted a FibroScan Clinic at Salem Gastro, where twelve patients were tested. On February 9, 2017, Premier conducted a second FibroScan Clinic at Salem Gastro. Relator did not attend this clinic and, therefore, does not know exactly how many patients received FibroScan tests.

277. On January 4, 2017, Premier conducted a FibroScan training session for three of Eugene Gastroenterology's medical assistants, during which six to eight patients were tested. On February 2, 2017, Premier conducted a FibroScan Clinic at Eugene Gastroenterology, where twelve patients were tested. On March 1, 2017, Premier conducted a second FibroScan Clinic at Eugene Gastroenterology. Relator did not attend this clinic and, therefore, does not know exactly how many patients received FibroScan tests.

278. Further, prior to leaving Premier, Relator arranged for a training session to be conducted at Anchorage Internal Medicine in March of 2017. Because Relator left Premier before the training and subsequent clinics occurred he does not know how many patients received tests.

279. All of these practices were high prescribers of HCV medications. For example, in 2015: Salem Gastroenterology sent 175 fills for Harvoni and Sovaldi to specialty pharmacies reimbursed under Medicare Part D; Gastroenterology Consultants sent 268 fills for Harvoni and Sovaldi to specialty pharmacies reimbursed under Medicare Part D; Eugene Gastroenterology sent 170 fills for Harvoni and Sovaldi to specialty pharmacies reimbursed under Medicare Part D; and Anchorage Internal Medicine sent 161 fills for Harvoni and Sovaldi to specialty pharmacies reimbursed under Medicare Part D. Thus, Premier sought to, and did in fact, induce practices to send their HCV prescriptions to Premier in return for performing FibroScan Clinics at their offices for their patients.

280. For example, Eugene Gastroenterology was a high volume HCV practice Relator called on while employed with Gilead. Although Relator directed Sovaldi and Harvoni prescriptions mainly to Bioplus, and later Premier, Eugene Gastroenterology primarily sent their prescriptions to Walgreen Specialty Pharmacy, which was located on the 1st floor of the same office building (Eugene Gastroenterology was on the 5th floor). The Walgreens sales

representative repeatedly reached out to Relator requesting that he direct Sovaldi and Harvoni prescriptions to Walgreens. The Walgreens representative further told Relator that the pharmacy scheduled two clinical pharmacists per shift so that one of them would always be available to provide individual or group HCV patient education either in the pharmacy or onsite at the practice's office so they did not have to hire someone for this role.

281. At the time, Eugene Gastroenterology was sending all of their HCV prescriptions to Walgreens because they agreed to allow any of their patients to come downstairs to their pharmacy for patient education and support. After Relator began working for Premier, he was able to convince the providers at Eugene Gastroenterology to send some of their HCV prescriptions to Premier by offering them Premier's extensive coverage/reimbursement services, including the performance of coverage determinations, benefit verifications, prior authorizations and coverage appeals. However, after Relator discussed and offered the FibroScan Clinics to Eugene Gastroenterology, the practice began to exclusively send all of their HCV prescriptions to Premier.

282. In addition, Relator listed, on Premier's shared FibroScan Clinic Tracker spreadsheet, the following high volume HCV prescribers' offices targeted for FibroScan Clinic meetings: Northwest Gastroenterology Clinic, LLC. 1130 NW 22nd Avenue, Suite 410, Portland, OR 97210; Dr. Justin Goodman, Gastroenterologist at The Polyclinic, 1145 Broadway, Seattle, WA 98122; Southlake Clinic Gastroenterology, 4011 Talbot Road Street, Fifth Floor, Renton, WA 98055; Infections Limited, 1624 South I Street, Suite 305 & 405, Tacoma, WA 98405; and Digestive Disease and Endoscopy Center, 3261 NW Mount Vintage Way, Suite 221, Silverdale, WA 98383.

283. As a result of conducting the FibroScan Clinics, Premier received a huge increase

in HCV prescriptions from the practices where the clinics were performed. The FibroScan Clinics resulted in so many new prescriptions from practices on the West Coast that Premier planned to ship their FibroScan machine to J.E. so he could conduct FibroScan Clinics in Idaho, Wyoming, and Montana to induce HCV prescriptions from providers in those states. Specifically, Premier sales representative J.E. and Echosens representative Q.D. held FibroScan Clinic meetings at Clearwater Gastroenterology, 2517 17th Street, Suite B, Lewiston, ID 83501, on January 24, 2017; at Idaho Gastroenterology Associates, 425 West Bannock Street, Boise, ID 83702, on January 25, 2017; and Digestive Health Clinic, 6259 West Emerald Street, Boise, ID 83704, on January 25, 2017. Further, J.E. and Q.D. listed, on Premier's shared FibroScan Clinic Tracker spreadsheet, that they planned to hold FibroScan Clinic meetings at Saint Luke's Gastroenterology Clinic, 775 Pole Line Rd West, Suite 203, Twin Falls, ID 83303; and Grand Teton Gastroenterology, 2770 Cortez Ave, Idaho Falls, ID 83404. Relator is aware that Premier intended for J.E. to schedule FibroScan Clinic meetings at high volume HCV providers' offices in Wyoming and Montana, that were not yet listed on the FibroScan Clinic Tracker.

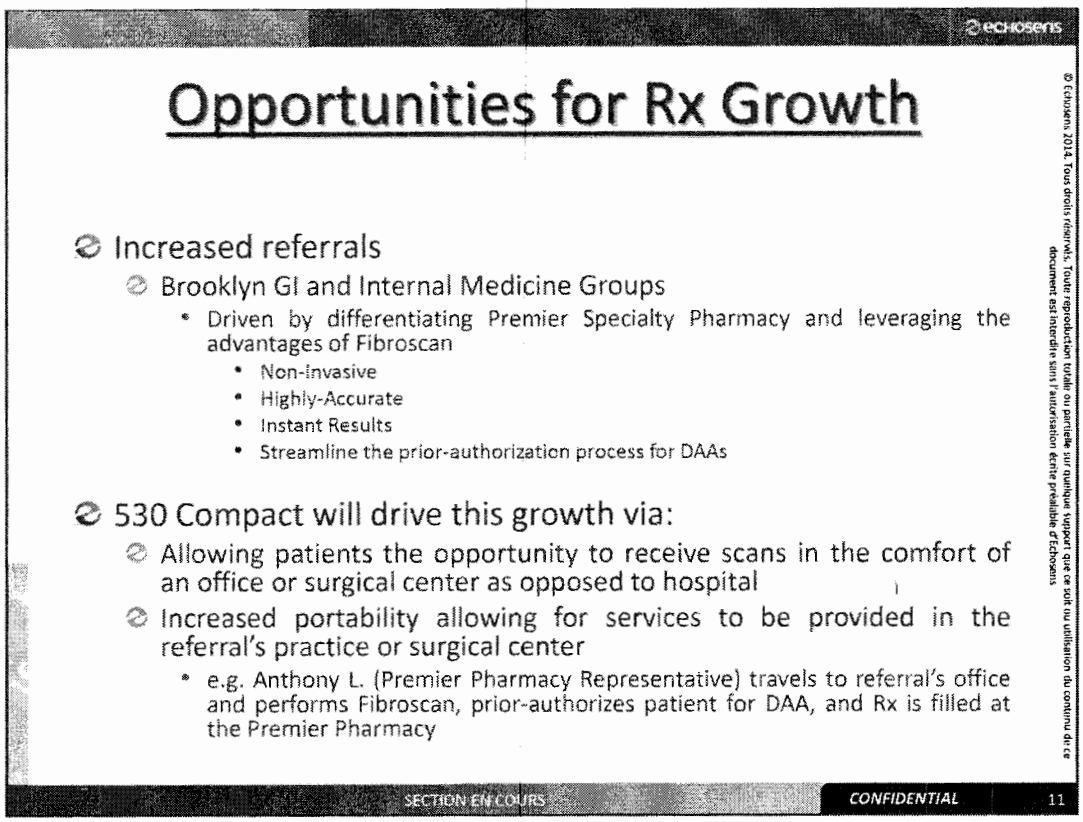
284. Premier also planned to ship their FibroScan machine to its sales representatives on the East coast for the same purpose. In fact, Premier even created a FibroScan Clinic pilot program presentation for the New York region. The presentation discusses the revenue potential for Premier from the FibroScan Clinics. The presentation states, in part, that:

> The FibroScan Clinics provide an "Immediate Revenue Opportunity" with "Immediate HCV Revenue Potential":
>
> Hepatitis C Treatment
>
> - $10,000 per Rx
> - 5-8 new Hepatitis C patients per month represents: $600,000-$960,000 per year

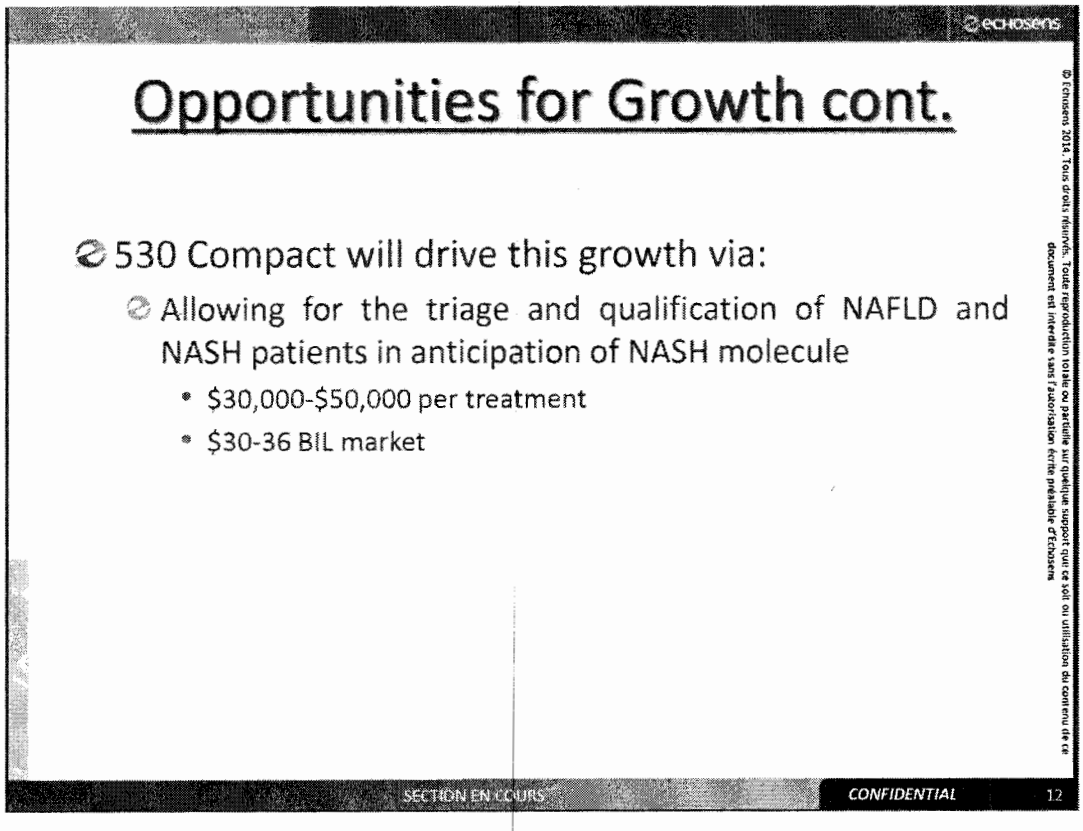
285. When Relator stopped working at Premier, it was in the process of ordering two or three more FibroScan systems from Echosens, at a lease price of $4,600, per month for each, for Premier sales representatives in the Central and East regions, with the intent of offering Premier FibroScan Clinics to health care providers in those regions.

286. As a result of the foregoing, Premier violated the AKS by providing in-kind remuneration in exchange for practices sending their HCV prescriptions to its pharmacy. Indeed, through the FibroScan Clinics, Premier allowed practices to save their patients a commute to a location that had a FibroScan machine, and allowed them the opportunity to bill for a service they would not otherwise have been able to bill for because they did not have a FibroScan machine. Further, through its FibroScan Clinics, practices could and did bill for a service, typically a high level E/M visit that they did not perform. This constitutes remuneration, and because it was provided with the intent to induce referrals, and referrals were induced, this conduct violates the AKS.

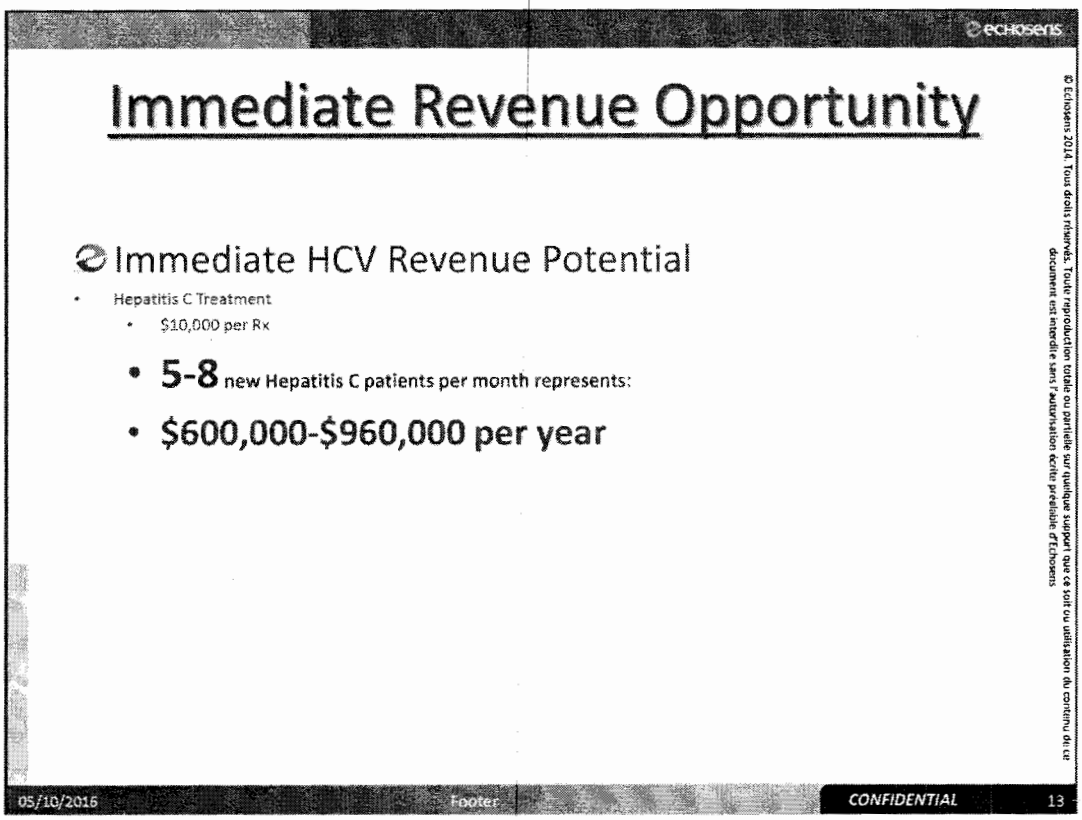
287. Several of Premier's own documents make clear that the FibroScan Clinics were nothing more than a way to provide remuneration to providers in exchange for prescriptions. For example, Premier created a PowerPoint presentation entitled "FibroScan 530 Compact Pilot Launch Program" to promote its clinics. One slide, entitled "Opportunities for Rx Growth," states:



288. The very next slide, entitled "Opportunities for Growth cont." states:

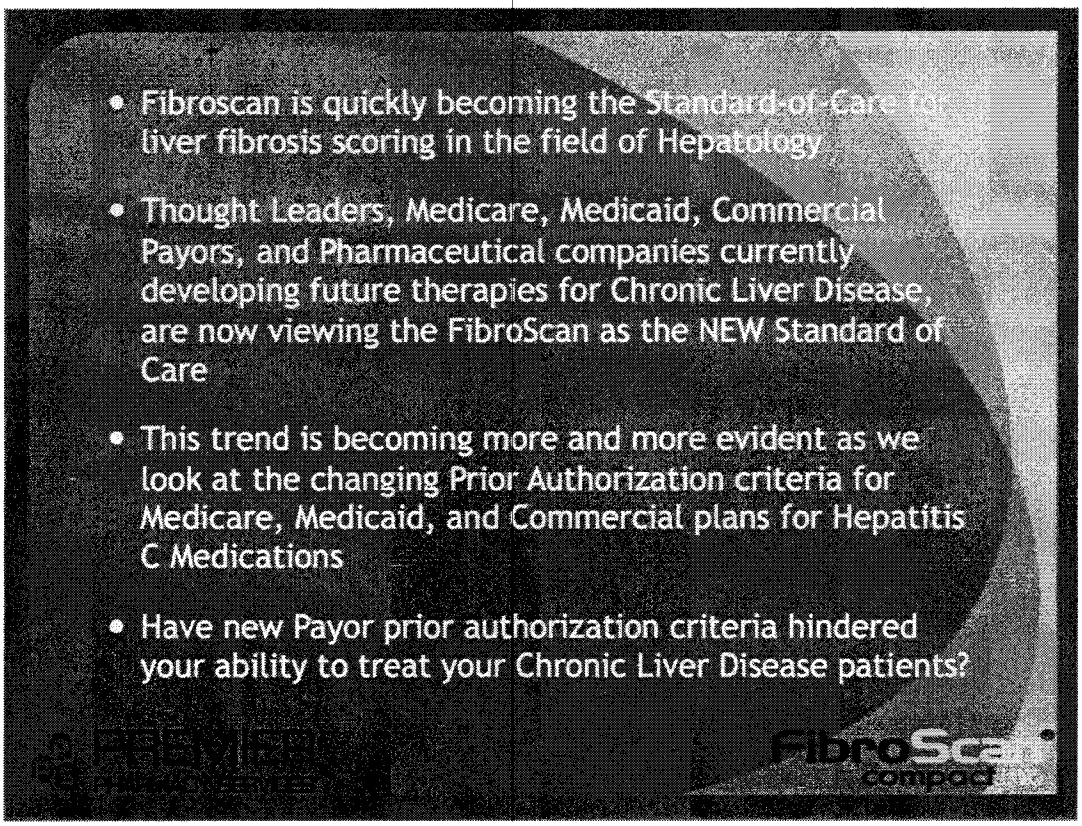


289. The following slide, entitled "Immediate Revenue Opportunity," states:



290. The above presentation makes clear that Premier was using its FibroScan Clinics to secure HCV medication prescriptions by providing FibroScan Clinics (i.e. in-kind remuneration) to practices. This conduct violates the AKS.

291. Premier created another PowerPoint presentation entitled "PREMIER PHARMACY SERVICES FibroScan Pilot Program" to promote its clinics. The first slide of the presentation, states:



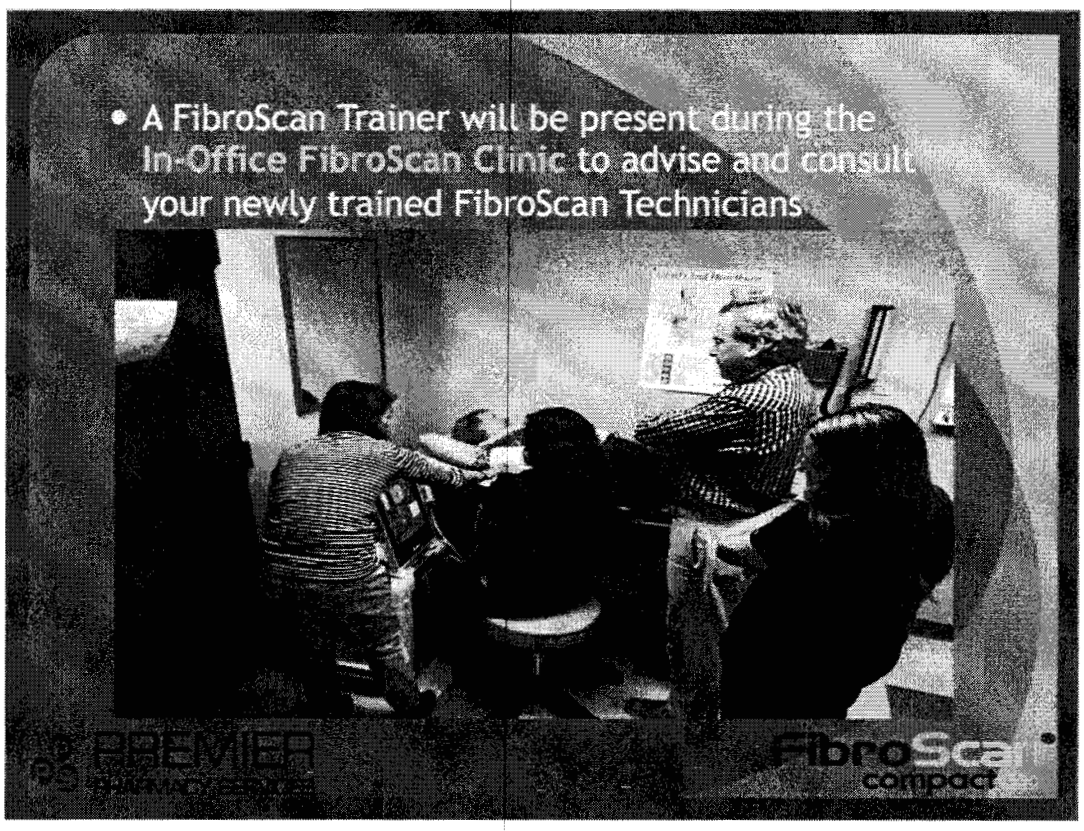
292. The next slide states:

293. A following slide states:

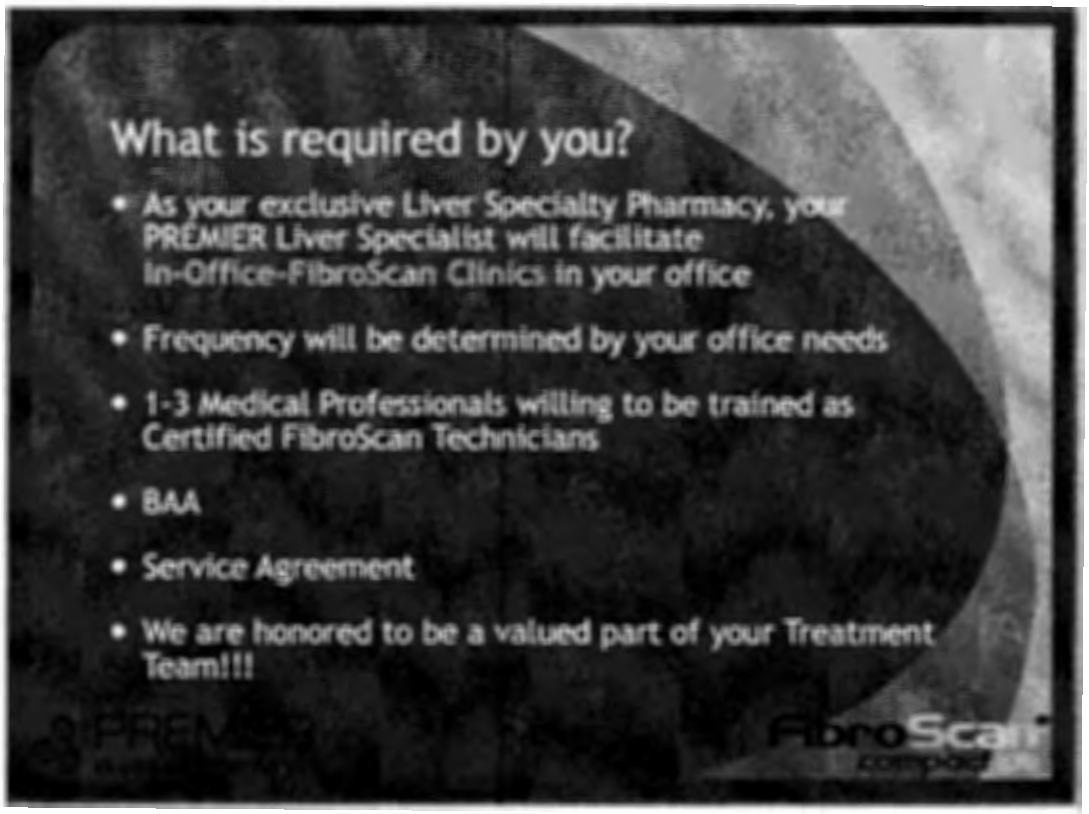
294. The very next three slides state:


How Does it Work?
• As your Specialty Pharmacy, in partnership with Echosens, we will conduct a scheduled In-Office FibroScan Clinic for your practice
• PREMIER PHARMACY will bring FibroScan to your patients!
PREMIER
FibroScan
compact


Echosens will train and certify YOUR staff in just ONE day!
FibroScan
compact



295. The last slide states:



296. The above presentation establishes that Premier was using its FibroScan Clinics and providing FibroScan training and certification to practices, to secure HCV medication prescriptions (i.e. in-kind remuneration). This conduct violates the AKS.

297. First, in the presentation, Premier begins by stating that payers, including Medicare, Medicaid, and commercial payers, view FibroScan as the "NEW standard of care" to obtain fibrosis scores that are a prior authorization prerequisite for HCV medications. The same slide asks the provider "Have new Payor prior authorization criteria hindered your ability to treat your Chronic Liver Disease patients?" The very next slide explains that through its FibroScan Clinics, Premier offers providers "unprecedented access" to FibroScan's technology by bringing its own FibroScan530C to their offices. In addition, Premier also offered providers' offices unlimited access to its FibroScan530C by stating, in the last slide, that the frequency of Premier's In-Office FibroScan Clinics would be determined by the office's needs. This is a clear indication that Premier intended to, and did, offer its FibroScan Clinics to healthcare providers who prescribe and refer the most HCV medications to its specialty pharmacy, and as a result Premier intended to host FibroScan Clinics more frequently in those offices.

298. Perhaps even more damaging, on the last slide of its presentation, Premier asked the provider, "What is required for you?" and answered, "As your **exclusive** Liver Specialty Pharmacy, your PREMIER Liver Specialist will provide In-Office-FibroScan Clinics in your office." (emphasis added). This statement clearly indicates that Premier would only provide FibroScan Clinics to providers who agreed, in exchange, to refer all HCV prescriptions to its specialty pharmacy.

299. Lastly, Premier's own brochure for the FibroScan Clinics confirms that this scheme violates the AKS. Specifically, the brochure states, in part, that:

Most practices do not have a FibroScan in-office and must refer their patients out to get this prerequisite test.

HOW DOES IT WORK

As your Specialty Pharmacy – in partnership with Echosens – we will conduct scheduled In-Office FibroScan Clinics for your practice. Your patient may not have access to a FibroScan, but we'll bring FibroScan to them!

- Premier Pharmacy will bring the FibroScan machine to your office.
- Echosens will train and certify YOUR staff, in just ONE day! In one day your staff can become Certified FibroScan Technicians and be able to run the FibcroScan test on your patients.
- A FibroScan Trainer will be present during the In-Office FibroScan Clinic to advise and consult your newly-trained FibroScan Technicians.
- Echosens provides the CPT codes for billing and reimbursement of the scan and reading of the scan.
- After the patient receives their FibroScan results, should a Provider recommend treatment, we will handle ALL the steps required to get the patient on therapy. In addition, your office will have the added benefits of working with our pharmacy:
    - Access to a Portal that provides real-time status, 24/7
    - A single point-of-contact with Premier's Concierge Service
    - White Glove Service with our Seamless Transfer Process

300. This brochure demonstrates that Premier's FibroScan Clinics were nothing more than a way to provide remuneration to providers in exchange for referrals.

301. First, the brochure acknowledges that most practices do not have a FibroScan and therefore must refer their patients to other providers to have this test performed. Then the brochure states "As your Specialty Pharmacy . . . we will conduct scheduled In-Office FibroScan Clinics for your practice . . ." and "Echosens will train and certify YOUR staff, in just ONE day! In one day your staff can become Certified FibroScan Technicians and be able to run the FibroScan test

on your patients." And, most importantly, "Echosens provides the CPT codes for billing and reimbursement of the scan and reading of the scan."

302. This brochure is telling because first it acknowledges that most practices do not have a FibroScan and therefore must refer patients to other providers to have the tests performed. Obviously, providers would prefer to be able to do these procedures in-house because they are billable and without a FibroScan they must pass up that billing opportunity. Next, the brochure mentions that Premier will bring the machine to the provider's office and train their staff on how to use it. Thus, Premier is using these clinics to induce providers to use its pharmacy by providing them with the ability to bill for a service they would not otherwise be able to bill for. Lastly, making clear that Premier intended that these clinics would induce providers to use their pharmacy, the brochure goes on to inform providers that they will be provided CPT codes to ensure correct billing of the FibroScan test.

303. Further, although the brochure states "As your Specialty Pharmacy," this was not the case. As detailed above, Relator and other sales representatives were going into practices that were not sending a majority of their prescriptions to Premier, and using these clinics to induce their prescriptions. The only purpose, therefore, that the aforementioned line can serve is to inform practices that these clinics are only available to practices that send their prescriptions to Premier. However, the brochure directs providers to send their prescriptions to Premier by stating that it will handle "ALL the steps required to get the patient on therapy," which Premier could only do if the prescription was sent to its pharmacy. This conduct violates the AKS.

304. Premier Specialty Pharmacy also provided in-kind remuneration to practices in exchange for HCV prescription referrals by offering them extraordinary RSS services. As discussed above, providers exhaust significant resources performing RSS functions, and removing

this burden is a significant value to providers and offers them a substantial incentive to refer all of their prescriptions for HCV medications to a specialty pharmacy who will perform the RSS services for them.

305. According to Relator, from at least October 2013 to present, Premier routinely provided extensive and complete RSS support to practices, meaning that it took over the entire RSS process for providers' offices in exchange for their HCV prescription referrals. For example, on October 2, 2014, R.P. sent a "Welcome" email to Relator. In the email, R.P. describes the RSS services that Premier provides to practices. R.P. states, in part:

> Get familiar with how we differentiate ourselves from the competitors:
>
> --We exhaust all avenues to ensure that we not only get the medications to the patient, but get it to them at the lowest out of pocket cost.
>
> --We offer seamless transition when medications have to be transferred. Look at the notes and see how we not only provide the phone number and contact person, but follow up to ensure delivery to the patient. I've been calling it white glove service. You can call it what ever you want, but no other pharmacy out there provides this kind of service.
>
> --We are open 24/7. If there is somehow a gap in service, we can provide shipment of meds—even on the weekends. (This is made possible because we service over 200 long term care facilities)
>
> --Real time, live data via the portal with the ability to view all patients sent to us and with one glance know where each patient is in the process.
>
> --Live chat, the ability to send notes to the pharmacy regarding each patient
>
> --Two dedicated PharmDs for HCV. They can be reached at the pharmacy or even their cell phone which is provided on the referral sheet.

306. In fact, on March 1, 2015, while Relator worked at Premier, they launched their HCV Concierge service, a team of dedicated Concierge representatives hired to be the one-point-of-contact for the provider offices assigned to them. On March 1, 2015, R.P. sent an email to the Premier HCV sales team to announce the Concierge Service launch. In the email R.P. states, in

part:

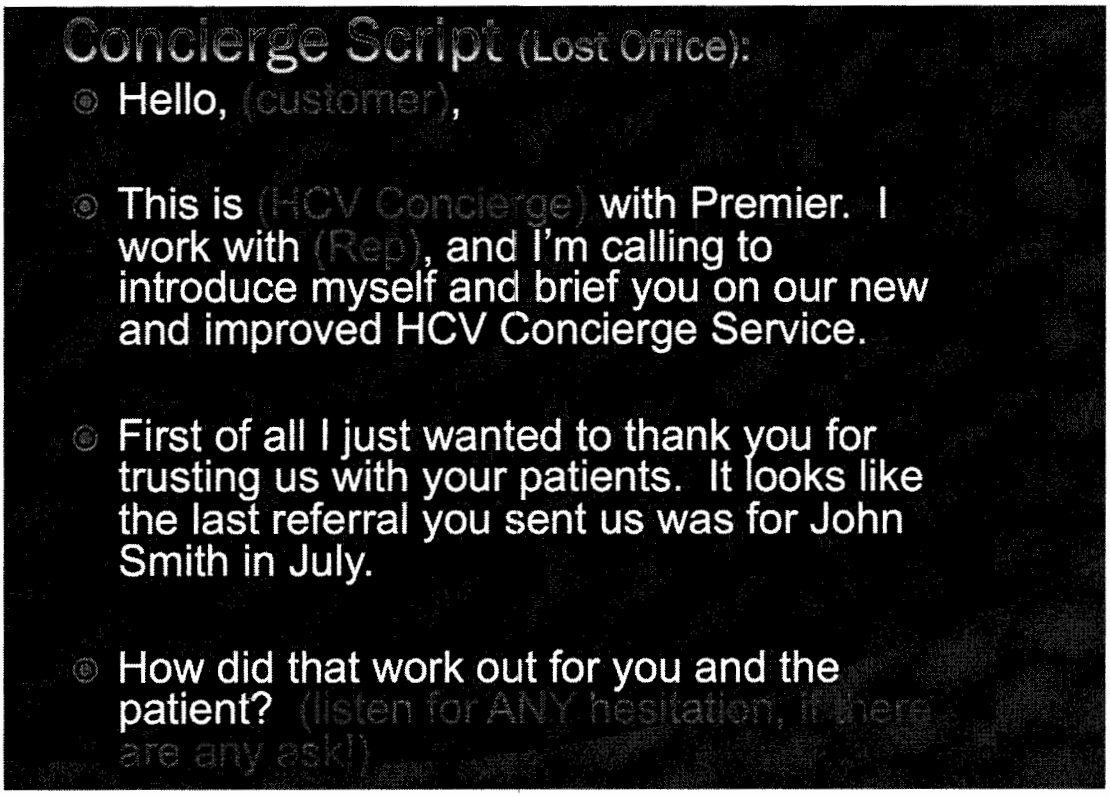
- Premier's pharmacies merged and all moved into a new facility in Baldwin Park, CA
- Premier's Concierge service will provide all their HCV accounts, ONE point of contact – a direct line with one Concierge assigned for each office.
- If HCV offices have a question, they call their Concierge, and will always get the same person to answer questions and cater to their needs.
- The Concierge will work with each office as they prefer: via phone, email, fax, or portal.
- When Premier needs additional missing information from a provider's office, they will get ONE Concierge that will be calling for ALL the patients within that office.

307. Further, Premier created and distributed a Concierge Service Menu to practices. The menu offered HCV prescribers' offices with RSS services options that could be specifically tailored according to their personal preference and the needs of their practice. Premier offered to perform all of the RSS for practices if they desired. For example, the first page of the menu included, among others things, the following options: a checkbox to elect not to switch prescribed therapy even if preferred by the Payer by electing to allow Premier to automatically submit a prior authorization for the prescribed HCV medication; a checkbox allowing Premier to appeal prior authorization denials (without involving the provider or provider's office staff); a checkbox allowing Premier to handle appeal denials (without involving the provider or provider's office staff); and on the menu's second page, Premier offers to provide the practices with offers to provide the HCPs' offices with an AOR Binder. An AOR (Appointment of Representative) is completed by a party seeking representation (i.e., the Medicare beneficiary, the provider or the supplier), giving authorization to another party to act as their representative in connection with medical claims. If selected, this option authorized Premier to: make any request; to present or to elicit evidence; to obtain appeals information; and to receive any notice in connection with appeals,

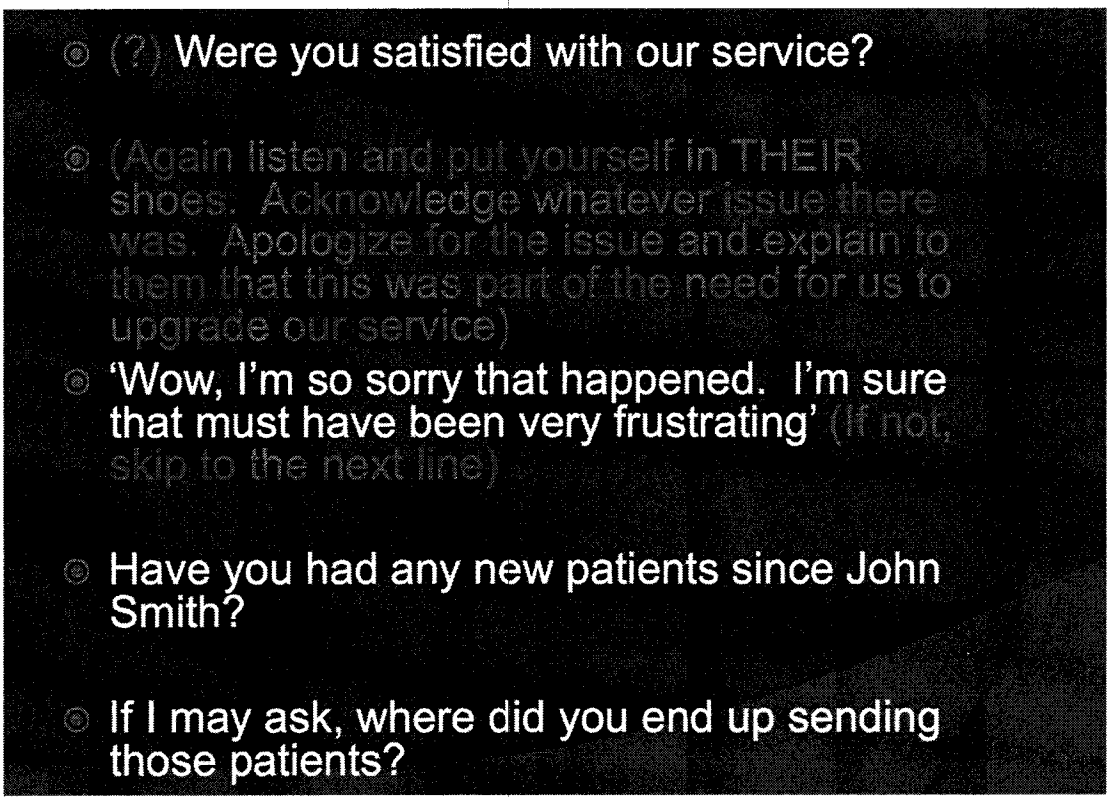
instead of the patient or provider; and authorized Premier to have access to the personal and medical patient information related appeals.

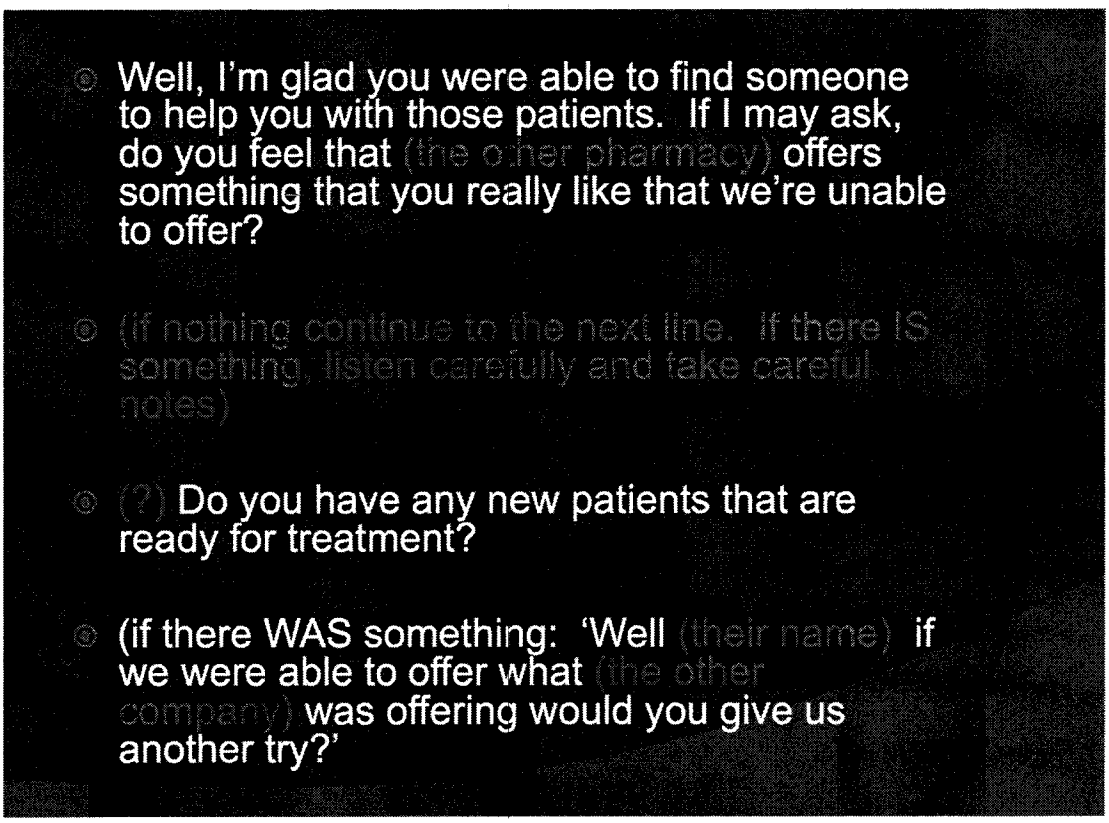
308. In November 2015, Premier held a Concierge Services Sales Training meeting where S.M. presented a PowerPoint presentation entitled, Concierge 2.0. The presentation provided a Concierge Script that provided the Concierge with a word for word script to follow on every call with HCV prescribers' offices.

309. Slide 24, entitled, "Concierge Script (Lost Office)", states:

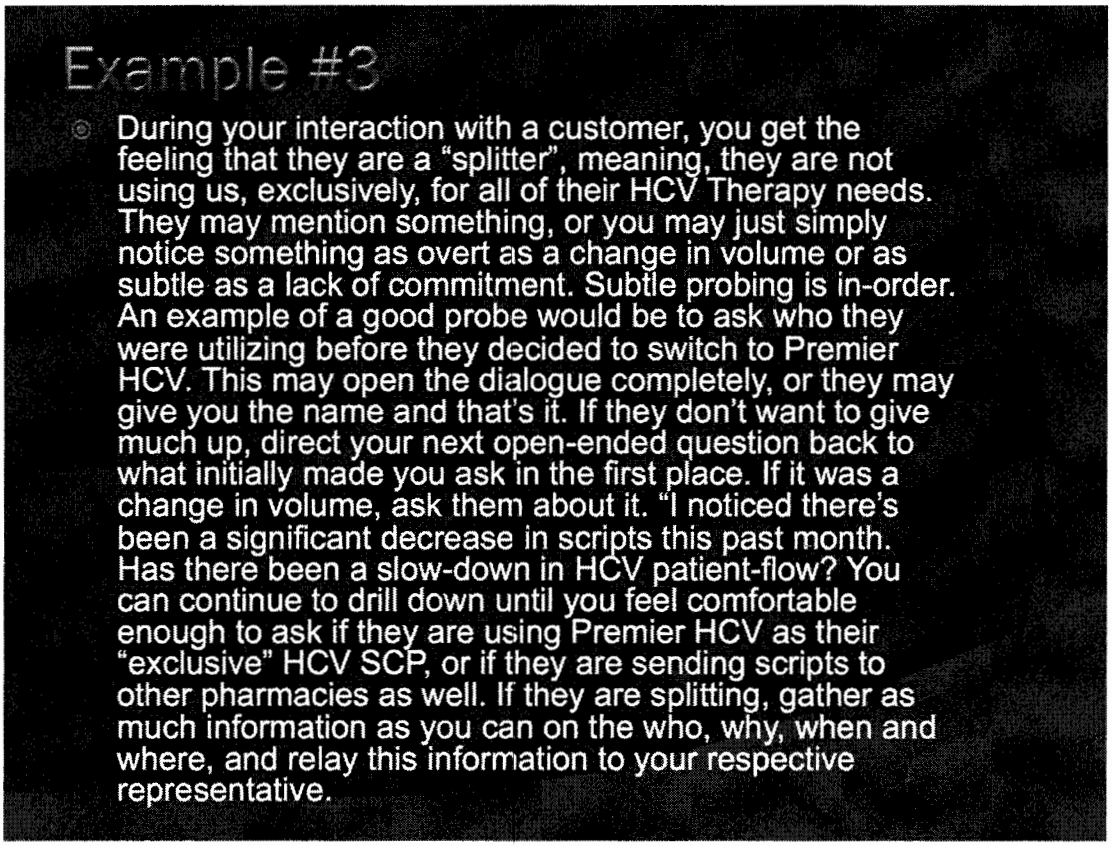


310. The following two slides state:

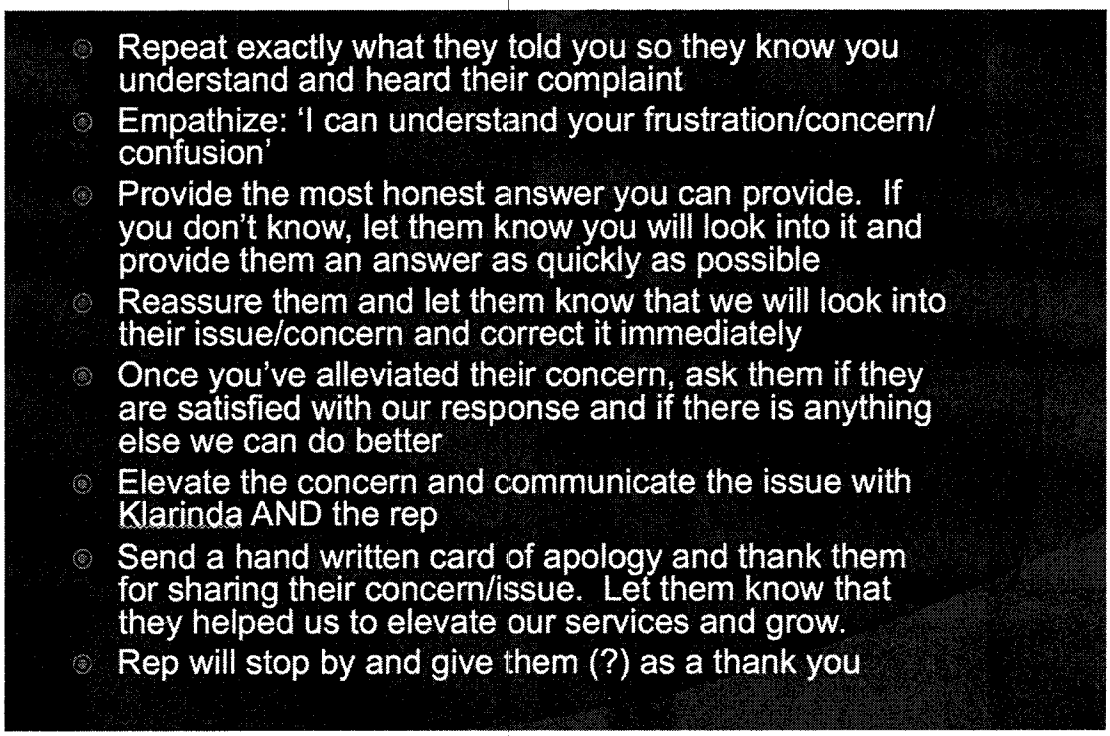




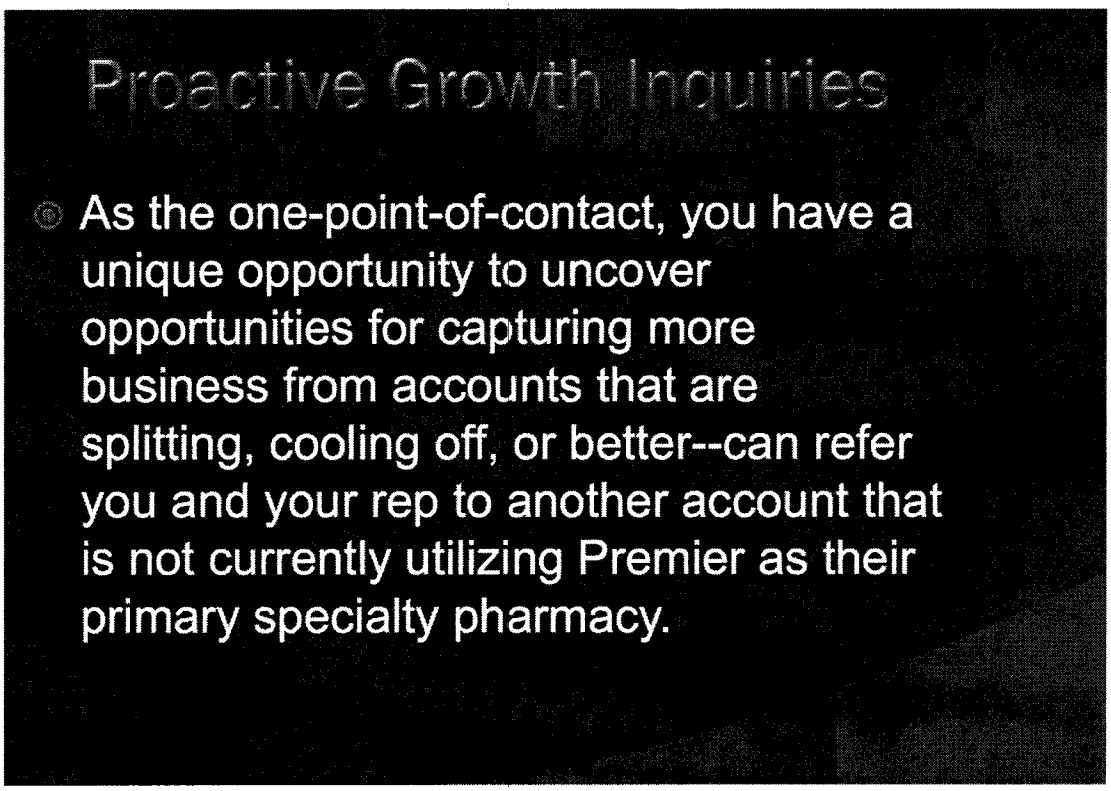
311. In the Concierge 2.0. Presentation, Premier further provided its Concierge team with examples of Personable Call Extenders. The third example, on slide 43, states:



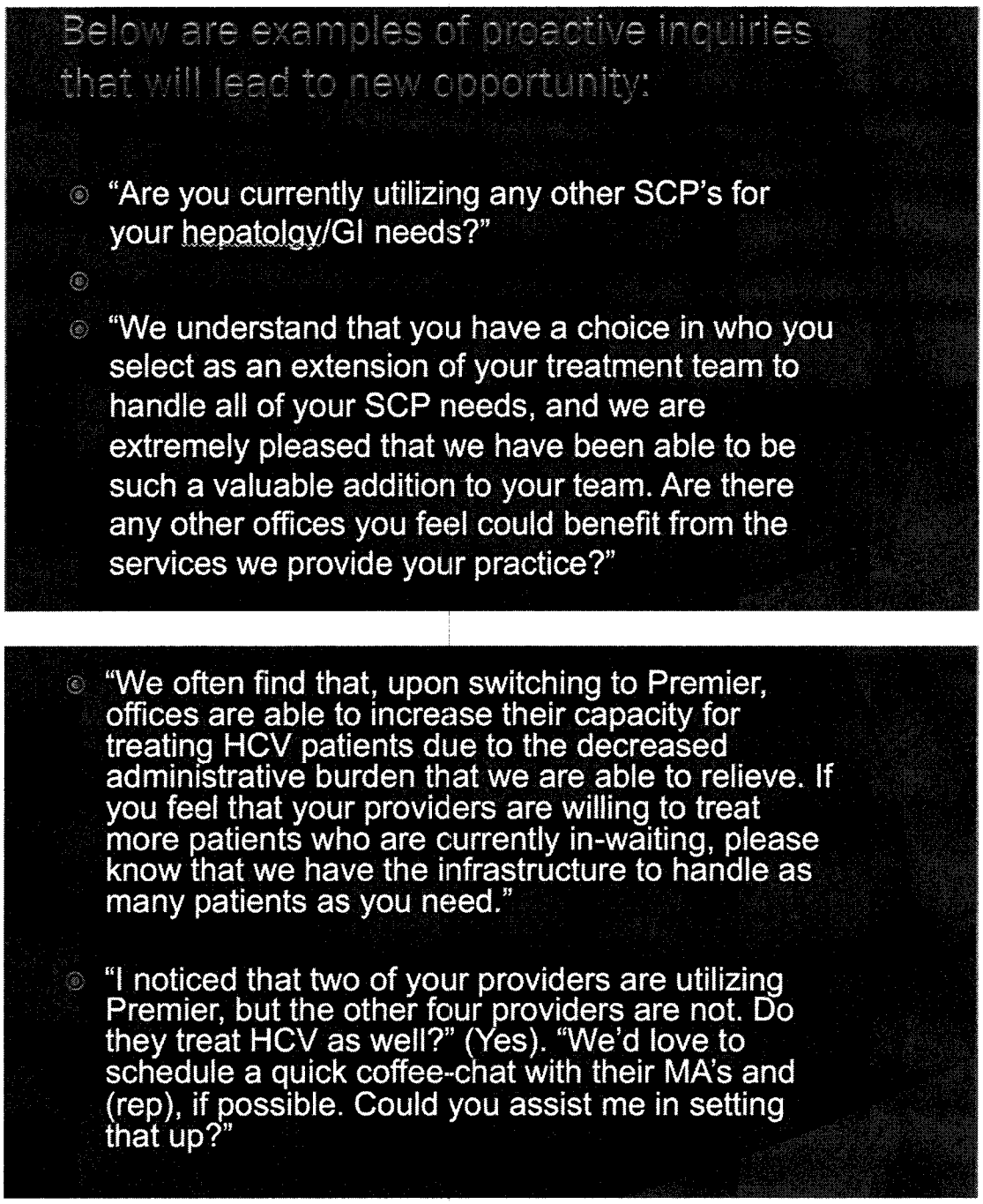
312. In the "Handling Issues" portion of the presentation, the Concierge team is coached to apologize and tell the provider that their sales representative "will stop by and give them (?), as a thank you." Slide 45 specifically states:



313. Slide 46, entitled, "Proactive Growth Inquiries", states:



314. The following two slide state:



315. The above presentation demonstrates that Premier indeed offered and provided in-kind remuneration in the form of RSS to practices to induce the referral of HCV prescriptions. In fact, throughout the presentation, the Concierge is coached to offer Premier's RSS and ask the providers for all of their HCV prescriptions. Further, in the case of a practice having a bad

experience with Premier, during the "Handling Issues" portion of the training presentation, the Concierge is coached to tell the provider that the sales representative would bring them a gift. Lastly, in coaching their Concierge team regarding "Proactive inquires that will lead to new opportunity," the Concierge is instructed to tell providers that "upon switching to Premier, offices are able to increase their capacity for treating HCV patients due to the decreased administrative burden that we are able to relieve." Thus, Premier describes its RSS as a revenue creating service, thereby providing value to the providers who switch to its specialty pharmacy. This is in-kind remuneration and violates the AKS.

COUNT I
(False Claims Act, 31 U.S.C. § 3729 *et seq.*)

316. Relator repeats each allegation in each of the proceeding paragraphs of this Complaint with the same force and effect as if set forth herein.

317. As described above, Defendants have submitted and/or caused to be submitted false or fraudulent claims to Medicare, Medicaid, and TriCare by submitting fraudulent bills to the Government (and/or through its conduct in causing others to submit fraudulent bills to the Government).

318. By virtue of the acts described above, Defendants have violated:

(1) 31 U.S.C. § 3729(a)(1)(A) by knowingly presenting, or causing to be presented, false or fraudulent claims for payment or approval; and/or

(2) 31 U.S.C. § 3729(a)(1)(B) by knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim;

(3) 31 U.S.C. § 3729(a)(1)(C) by conspiring to commit a violation of subparagraphs (A), (B), and (C); and/or

(4) 31 U.S.C. § 3729(a)(1)(G) by knowingly making, using, or causing to be

made or used, a false record or statement material to an obligation to pay or transit money or property to the Government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the Government;

319. To the extent any of the conduct alleged herein occurred on or before May 20, 2009, Relator realleges that Defendants knowingly violated 31 U.S.C. §§ 3729(a)(1)-(3), (7) prior to amendment, by engaging in the above-described conduct.

320. By reason of the foregoing, the United States has suffered actual damages and is entitle to recover treble damages plus a civil monetary penalty for each false claim.

WHEREFORE, Relator pray that the Court enter judgment against Defendants as follows:

(a) that the United States be awarded damages in the amount of three times the damages sustained by the United States because of the false claims alleged within this Complaint, as the Federal False Claims Act, 31 U.S.C. § 3729 *et seq*., provides;

(b) that civil penalties of $21,730 be imposed for each and every false claim that Defendants caused to be presented to the United States and/or its grantees, and for each false record or statement that Defendants made, used, or caused to be made or used that was material to a false or fraudulent claim;

(c) that attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case be awarded;

(d) that Relator be awarded the maximum amount allowed to them pursuant to the False Claims Act; and

(e) that this Court order such other and further relief as it deems proper.

COUNT II
(California False Claims Act, Cal. Gov't Code § 12650 *et seq.*)

321. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

322. This is a *qui tam* action brought by Relator on behalf of the State of California to recover treble damages and civil penalties under the California False Claims Act, Cal. Gov't Code § 12650 *et seq.*

323. Cal. Gov't Code § 12651(a) provides liability for any person who:

(1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval.

(2) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim.

(3) Conspires to commit a violation of this subdivision.

(4) Has possession, custody, or control of public property or money used or to be used by the state or by any political subdivision and knowingly delivers or causes to be delivered less than all of that property.

(5) Is authorized to make or deliver a document certifying receipt of property used or to be used by the state or by any political subdivision and knowingly makes or delivers a receipt that falsely represents the property used or to be used.

(6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from any person who lawfully may not sell or pledge the property.

(7) Knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the state or to any political subdivision, or knowingly conceals or knowingly and improperly avoids, or decreases an obligation to pay or transmit money or property to the state or to any political subdivision.

(8) Is a beneficiary of an inadvertent submission of a false claim, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

324. Defendants violated Cal. Gov't Code § 12651(a) and knowingly caused false claims

to be made, used and presented to the State of California by engaging in the conduct alleged herein and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded health care programs.

325. The State of California, by and through the California Medicaid program and other state health care programs, and unaware of Defendants' conduct, paid the claims submitted by health care providers and third party payers in connection therewith.

326. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of California in connection with Defendants' conduct. Compliance with applicable California statutes was also a condition of payment of claims submitted to the State of California.

327. Had the State of California known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

328. As a result of Defendants' violations of Cal. Gov't Code § 12651(a), the State of California has been damaged in an amount far in excess of millions of dollars exclusive of interest.

329. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Cal. Gov't Code § 12652(c) on behalf of themselves and the State of California.

330. This Court is requested to accept supplemental jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate

damages to the State of California in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF CALIFORNIA:

(1) Three times the amount of actual damages which the State of California has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants presented or caused to be presented to the State of California;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Cal. Gov't Code § 12652 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT III
(Colorado Medicaid False Claims Act, C.R.S.A. § 25.5-4-304 *et seq.*)

331. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

332. This is a *qui tam* action brought by Relator on behalf of the State of Colorado to recover treble damages and civil penalties under the Colorado Medicaid False Claims Act, C.R.S.A. § 25.5-4-304 *et seq.*

333. Colorado's Medicaid False Claims Act, C.R.S.A. § 25.5-4-305 *et seq.*, provides for liability for any person who:

(a) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(b) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim;

(c) Has possession, custody, or control of property or money used, or to be used, by the state in connection with the "Colorado Medical Assistance Act" and knowingly delivers, or causes to be delivered, less than all of the money or property;

(d) Authorizes the making or delivery of a document certifying receipt of property used, or to be used, by the state in connection with the "Colorado Medical Assistance Act" and, intending to defraud the state, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(e) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the state in connection with the "Colorado Medical Assistance Act" who lawfully may not sell or pledge the property;

(f) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state in connection with the "Colorado Medical Assistance Act", or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state in connection with the "Colorado Medical Assistance Act"; or

(g) Conspires to commit a violation of paragraphs (a) to (f) of this subsection (1).

334. Defendants violated the Colorado Medicaid False Claims Act and knowingly caused false claims to be made, used and presented to the State of Colorado by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

335. The State of Colorado, by and through the Colorado Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by

healthcare providers and third party payers in connection therewith.

336. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Colorado in connection with Defendants' conduct. Compliance with applicable Colorado statutes was also a condition of payment of claims submitted to the State of Colorado.

337. Had the State of Colorado known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

338. As a result of Defendants' violations of the Colorado Medicaid False Claims Act, the State of Colorado has been damaged in an amount far in excess of millions of dollars exclusive of interest.

339. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Colorado Medicaid False Claims Act on behalf of himself and the State of Colorado.

340. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Colorado in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF COLORADO:

(1) Three times the amount of actual damages which the State of Colorado has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Colorado, except that this upper limit on liability is subject to an automatic adjustment in accordance with the federal Civil Penalties Inflation Adjustment Act of 1990 ("CPIAA");

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Colorado Medicaid False Claims Act and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT IV
(Connecticut False Claims Act, Conn. Gen. Stat. § 17b-301a *et seq.*)

341. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

342. This is a *qui tam* action brought by Relator on behalf of the State of Connecticut to recover treble damages and civil penalties under the Connecticut False Claims Act, Conn. Gen. Stat. § 17b-301a *et seq.*

343. Conn. Gen. Stat. § 4-275 imposes liability as follows:

(a) No person shall:

(1) Knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval under a state-administered health or human services program;

(2) Knowingly make, use or cause to be made or used, a false

record or statement material to a false or fraudulent claim under a state-administered health or human services program;

(3) Conspire to commit a violation of this section;

(4) Having possession, custody or control of property or money used, or to be used, by the state relative to a state-administered health or human services program, knowingly deliver, or cause to be delivered, less property than the amount for which the person receives a certificate or receipt;

(5) Being authorized to make or deliver a document certifying receipt of property used, or to be used, by the state relative to a state-administered health or human services program and intending to defraud the state, make or deliver such document without completely knowing that the information on the document is true;

(6) Knowingly buy, or receive as a pledge of an obligation or debt, public property from an officer or employee of the state relative to a state-administered health or human services program, who lawfully may not sell or pledge the property;

(7) Knowingly make, use or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state under a state-administered health or human services program; or

(8) Knowingly conceal or knowingly and improperly avoid or decrease an obligation to pay or transmit money or property to the state under a state-administered health or human services program.

344. Defendants violated the Connecticut False Claims Act and knowingly caused false claims to be made, used and presented to the State of Connecticut by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

345. The State of Connecticut, by and through the Connecticut Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted

by healthcare providers and third party payers in connection therewith.

346. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Connecticut in connection with Defendants' conduct. Compliance with applicable Connecticut statutes was also a condition of payment of claims submitted to the State of Connecticut.

347. Had the State of Connecticut known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

348. As a result of Defendants' violations of the Connecticut False Claims Act, the State of Connecticut has been damaged in an amount far in excess of millions of dollars exclusive of interest.

349. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Connecticut False Claims Act on behalf of himself and the State of Connecticut.

350. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Connecticut in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF CONNECTICUT:

(1) Three times the amount of actual damages which the State of Connecticut has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Connecticut, except that this upper limit on liability is subject to an automatic adjustment in accordance with the CPIAA;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Connecticut False Claims Act, Conn. Gen. Stat. § 4-275 *et seq.* and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT V

(Delaware False Claims and Reporting Act, 6 Del. C. Ann. tit. 6 § 1201 *et seq.*)

351. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

352. This is a *qui tam* action brought by Relator on behalf of the State of Delaware to recover treble damages and civil penalties under the Delaware False Claims and Reporting Act, 6 Del. C. Ann. tit. 6 § 1201 *et seq.*

353. 6 Del. C. § 1201(a) in pertinent part provides for liability for any person who:

(1) Knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;

(2) Knowingly makes, uses or causes to be made or used a false record or statement material to a false or fraudulent claim;

> (3) Conspires to commit a violation of paragraph (a)(1), (2), . . . or (7) of this section; or
>
> * * *
>
> (7) Knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

354. Defendants furthermore violated the Delaware False Claims and Reporting Act, 6 Del. C. Ann. tit. 6 § 1201 *et seq.*, and knowingly caused false claims to be made, used and presented to the State of Delaware by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

355. The State of Delaware, by and through the Delaware Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

356. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Delaware in connection with Defendants' conduct. Compliance with applicable Delaware statutes and regulations was also an express condition of payment of claims submitted to the State of Delaware.

357. Had the State of Delaware known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

358. As a result of Defendants' violations of the Delaware False Claims and Reporting Act, 6 Del. C. Ann. tit. 6 § 1201 *et seq.*, the State of Delaware has been damaged in an amount far in excess of millions of dollars exclusive of interest.

359. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Delaware False Claims and Reporting Act, 6 Del. C. Ann. tit. 6 § 1201 *et seq.*, on behalf of himself and the State of Delaware.

360. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Delaware in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF DELAWARE:

(1) Three times the amount of actual damages which the State of Delaware has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Delaware;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Delaware False Claims and Reporting Act, 6 Del. C. Ann. tit. 6 § 1201, and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT VI
(Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*)

361. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

362. This is a *qui tam* action brought by Relator on behalf of the State of Florida to recover treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*

363. Fla. Stat. § 68.082(2) provides liability for any person who:

(a) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;

(b) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim; or

(c) Conspires to commit a violation of this subsection.

364. Defendants further violated Fla. Stat. § 68.082(2) and knowingly caused false claims to be made, used and presented to the State of Florida by engaging in the conduct alleged herein and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

365. The State of Florida, by and through the Florida Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

366. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Florida in connection with Defendants' conduct. Compliance with applicable Florida statutes was also a condition of payment of claims submitted to the State of Florida.

367. Had the State of Florida known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

368. As a result of Defendants' violations of Fla. Stat. § 68.082(2), the State of Florida has been damaged in an amount far in excess of millions of dollars exclusive of interest.

369. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Fla. Stat. § 68.083(2) on behalf of himself and the State of Florida.

370. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF FLORIDA:

(1) Three times the amount of actual damages which the State of Florida has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Florida;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Fla. Stat. § 68.085 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT VII

(Georgia False Medicaid Claims Act, Ga. Code Ann., § 49-4-168 *et seq.*)

371. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

372. This is a *qui tam* action brought by Relator on behalf of the State of Georgia to recover treble damages and civil penalties under the Georgia False Medicaid Claims Act, Ga. Code Ann., § 49-4-168 *et seq.*

373. The Georgia False Medicaid Claims Act, Ga. Code Ann., § 49-4-168-1, imposes liability on any person who:

(1) Knowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim;

(3) Conspires to commit a violation of paragraph (1), (2), (4), (5), (6), or (7) of this subsection;

(4) Has possession, custody, or control of property or money used or to be used by the Georgia Medicaid program and knowingly delivers, or causes to be delivered, less than all of such property or money;

(5) Is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Georgia Medicaid program and, intending to defraud the Georgia Medicaid program, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Georgia Medicaid program who lawfully may not sell or pledge the property; or

(7) Knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit property or money to the Georgia Medicaid program, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit property or money to the Georgia Medicaid program.

374. Defendants violated the Georgia False Medicaid Claims Act and knowingly caused false claims to be made, used and presented to the State of Georgia by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

375. The State of Georgia, by and through the Georgia Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

376. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Georgia in connection with Defendants' conduct. Compliance with applicable Georgia statutes was also a condition of payment of claims submitted to the State of Georgia.

377. Had the State of Georgia known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

378. As a result of Defendants' violations of the Georgia False Medicaid Claims Act, the State of Georgia has been damaged in an amount far in excess of millions of dollars exclusive

of interest.

379. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Georgia False Medicaid Claims Act on behalf of himself and the State of Georgia.

380. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Georgia in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF GEORGIA:

(1) Three times the amount of actual damages which the State of Georgia has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Georgia;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Georgia False Medicaid Claims Act, Ga. Code Ann., § 49-4-168, and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT VIII
(Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*)

381. Relator realleges and incorporates by reference the prior paragraphs as though fully

set forth herein.

382. This is a *qui tam* action brought by Relator on behalf of the State of Hawaii to recover treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*

383. Section 661-21(a) provides liability for any person who:

> (1) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> * * *
>
> (6) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals, or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State; or
>
> * * *
>
> (8) Conspires to commit any of the conduct described in this subsection.

384. Defendants violated Haw. Rev. Stat. § 661-21(a) and knowingly caused false claims to be made, used and presented to the State of Hawaii by the conduct alleged herein and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

385. The State of Hawaii, by and through the Hawaii Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

386. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Hawaii in connection with Defendants' conduct. Compliance with

applicable Hawaii statutes was also a condition of payment of claims submitted to the State of Hawaii.

387. Had the State of Hawaii known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

388. As a result of Defendants' violations of Haw. Rev. Stat. § 661-21, the State of Hawaii has been damaged in an amount far in excess of millions of dollars exclusive of interest.

389. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Haw. Rev. Stat. § 661-21 on behalf of himself and the State of Hawaii.

390. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Hawaii in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF HAWAII:

(1) Three times the amount of actual damages which the State of Hawaii has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Hawaii;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Haw. Rev. Stat. § 661-21 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT IX
(Illinois False Claims Act, 740 ILCS 175/1 *et seq.*)

391. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

392. This is a *qui tam* action brought by Relator on behalf of the State of Illinois to recover treble damages and civil penalties under the Illinois False Claims Act, 740 ILCS 175/1 *et seq.*

393. 740 ILCS 175/3(a) provides liability for any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the State a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

(3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

394. Defendants violated 740 ILCS 175/3(a) and knowingly caused false claims to be made, used and presented to the State of Illinois by its deliberate and systematic violation of federal and state laws by engaging in the conduct alleged herein and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

395. The State of Illinois, by and through the Illinois Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

396. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Illinois in connection with Defendants' conduct. Compliance with applicable Illinois statutes was also a condition of payment of claims submitted to the State of Illinois.

397. Had the State of Illinois known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

398. As a result of Defendants' violations of 740 ILCS 175/3(a), the State of Illinois has been damaged in an amount far in excess of millions of dollars exclusive of interest.

399. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 740 ILCS 175/3(b) on behalf of himself and the State of Illinois.

400. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Illinois in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF ILLINOIS:

(1) Three times the amount of actual damages which the State of Illinois has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Illinois;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 740 ILCS 175/4(d) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT X

(Illinois Insurance Claims Fraud Prevention Act, 740 Ill. Comp. Stat. §§ 92/1 *et seq.*)

401. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

402. This is a claim for treble damages and penalties under the IICFPA.

403. Pursuant to 740 Ill. Comp. Stat. § 92/5(a):

> A person who violates any provision of this Act, . . . or Section 17-10.5 of the Criminal Code . . . shall be subject, in addition to any other penalties that may be prescribed by law, to a civil penalty of not less than $5,000 nor more than $10,000, plus an assessment of not more than 3 times the amount of each claim for compensation under a contract of insurance.

404. 720 Ill. Comp. Stat. § 5/17-10.5 provides, in pertinent part:

(a) Insurance fraud.

(1) A person commits insurance fraud when he or she knowingly obtains,

> attempts to obtain, or causes to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false claim or by causing a false claim to be made on any policy of insurance issued by an insurance company or by the making of a false claim or by causing a false claim to be made to a self-insured entity, intending to deprive an insurance company or self-insured entity permanently of the use and benefit of that property.
>
> (2) A person commits health care benefits fraud against a provider, other than a governmental unit or agency, when he or she knowingly obtains or attempts to obtain, by deception, health care benefits and that obtaining or attempt to obtain health care benefits does not involve control over property of the provider.
>
> * * *
>
> (c) Conspiracy to commit insurance fraud. . . .

405. By virtue of the acts described above, Gilead knowingly presented or caused to be presented false or fraudulent claims to the private insurers in Illinois, or for patients in Illinois that those insurers covered, for payment or approval in violation of each patient's private health insurance contract.

406. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used false records and statements and omitted material facts to induce the private insurers in Illinois, or for patients in Illinois covered by those insurers, to approve or pay such false and fraudulent claims.

407. Gilead knowingly presented or caused to be presented false or fraudulent claims to the private insurers in Illinois, or for patients in Illinois those insurers covered, for payment or approval in violation of each patient's private health insurance contract.

408. By virtue of the acts described above, Gilead knowingly utilized a scheme by which it presented, or caused to be presented, false or fraudulent claims to private insurers in Illinois, or for patients in Illinois that those insurers covered (i.e., patients who hold private insurance

contracts and against whom Gilead could file claims for payment or approval) in violation of each patient's private health insurance contract.

409. By virtue of the acts described above, Gilead conspired to violate the IICFPA and each patient's private health insurance contract.

410. The private insurers in Illinois, or those insurers that covered patients in Illinois, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be presented by Gilead, paid and continue to pay the claims that are non-payable as a result of Gilead's illegal conduct.

411. Gilead knowingly submitted and/or caused to be made or used false records or false statements in order to avoid or decrease its obligations to return overpayments to these private insurance companies.

412. By reason of Gilead's acts, these private insurance companies have been damaged, and continue to be damaged, in a substantial amount to be determined at trial.

413. Each claim for reimbursement that was a result of Gilead's scheme represents a false or fraudulent record or statement and a false or fraudulent claim for payment.

414. State of Illinois is entitled to the maximum penalty of $10,000 per violation, plus an assessment of three times the amount of each false or fraudulent claim for compensation made, used, presented, or caused to be made, used, or presented by Gilead.

COUNT XI

(Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5 *et seq.*)

415. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

416. This is a *qui tam* action brought by Relator on behalf of the State of Indiana to recover treble damages and civil penalties under the Indiana False Claims and Whistleblower

Protection Act, Ind. Code 5-11-5.5, which imposes liability on:

> (b) A person who knowingly or intentionally:
>
> (1) presents a false claim to the state for payment or approval;
>
> (2) makes or uses a false record or statement to obtain payment or approval of a false claim from the state;
>
> (3) with intent to defraud the state, delivers less money or property to the state than the amount recorded on the certificate or receipt the person receives from the state;
>
> (4) with intent to defraud the state, authorizes issuance of a receipt without knowing that the information on the receipt is true;
>
> (5) receives public property as a pledge of an obligation on a debt from an employee who is not lawfully authorized to sell or pledge the property;
>
> (6) makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state;
>
> (7) conspires with another person to perform an act described in subdivisions (1) through (6); or
>
> (8) causes or induces another person to perform an act described in subdivisions (1) through (6) ....

417. Defendants violated the Indiana False Claims Act and knowingly caused false claims to be made, used and presented to the State of Indiana by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

418. The State of Indiana, by and through the Indiana Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

419. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid

and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Indiana in connection with Defendants' conduct. Compliance with applicable Indiana statutes was also a condition of payment of claims submitted to the State of Indiana.

420. Had the State of Indiana known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

421. As a result of Defendants' violations of Indiana's False Claims Act, the State of Indiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

422. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Ind. Code § 5-11-5.5 *et seq.* on behalf of himself and the State of Indiana.

423. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Indiana in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF INDIANA:

(1) Three times the amount of actual damages which the State of Indiana has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,000 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Indiana, except that this upper limit on liability is subject to an automatic adjustment in

accordance with the CPIAA;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Ind. Code § 5-11-5.5 *et seq.* and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XII
(Iowa False Claims Law, I.C.A. § 685.1 *et seq.*)

424. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

425. This is a *qui tam* action brought by Relator on behalf of the State of Iowa to recover treble damages and civil penalties under the Iowa False Claims Law, I.C.A. § 685.1 *et seq.*

426. Iowa False Claims Law, I.C.A. § 685.2, in pertinent part provides for liability for any person who:

(a) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.

(b) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.

(c) Conspires to commit a violation of paragraph "a", "b"....

427. Defendants violated the Iowa False Claims Law, I.C.A. § 685.1 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Iowa by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims

submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

428. The State of Iowa, by and through the Iowa Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

429. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Iowa in connection with Defendants' conduct. Compliance with applicable Iowa statutes was also a condition of payment of claims submitted to the State of Iowa.

430. Had the State of Iowa known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

431. As a result of Defendants' violations of the Iowa False Claims Law, I.C.A. § 685.1 *et seq*., the State of Iowa has been damaged in an amount far in excess of millions of dollars exclusive of interest.

432. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Iowa False Claims Law, I.C.A. § 685.1 *et seq*., on behalf of himself and the State of Iowa.

433. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Iowa in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF IOWA:

(1) Three times the amount of actual damages which the State of Iowa has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Iowa, except that this upper limit on liability is subject to an automatic adjustment in accordance with the CPIAA;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Iowa False Claims Law, I.C.A. § 685.1 *et seq*. and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XIII

(Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:437.1 *et seq.*)

434. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

435. This is a *qui tam* action brought by Relator on behalf of the State of Louisiana to recover treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 437.1 *et seq.*

436. La. Rev. Stat. Ann. § 46:438.3 provides:

(A) No person shall knowingly present or cause to be presented a false or fraudulent claim.

(B) No person shall knowingly engage in misrepresentation or make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim.

(C) No person shall knowingly make, use, or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the medical assistance programs, or to knowingly conceal, avoid, or decrease an obligation to pay or transmit money or property to the medical assistance programs.

(D) No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim.

437. Defendants further violated La. Rev. Stat. Ann. §46:438.3 and knowingly caused false claims to be made, used and presented to the State of Louisiana by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

438. The State of Louisiana, by and through the Louisiana Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

439. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Louisiana in connection with Defendants' conduct. Compliance with applicable Louisiana statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Louisiana.

440. Had the State of Louisiana known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct

failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

441. As a result of Defendants' violations of La. Rev. Stat. Ann. § 46:438.3, the State of Louisiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

442. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to La. Rev. Stat. Ann. §46:439.1(A) on behalf of himself and the State of Louisiana.

443. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Louisiana in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF LOUISIANA:

(1) Three times the amount of actual damages which the State of Louisiana has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,000 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Louisiana, except that this upper limit on liability is subject to an automatic adjustment in accordance with the CPIAA;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to La. Rev. Stat. § 439.4(A) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XIV

(Maryland False Claims Act, Md. Code Ann. Health - Gen., § 2-601 *et seq.*)

444. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

445. This is a *qui tam* action brought by Relator on behalf of the State of Maryland to recover treble damages and civil penalties under the Maryland False Claims Act, Md. Code Ann. Health - Gen., § 2-601 *et seq.*

446. Section 2-602 of Maryland's False Claims Act imposes liability as follows:

(a) A person may not:

(1) Knowingly present or cause to be presented a false or fraudulent claim for payment or approval;

(2) Knowingly make, use, or cause to be made or used a false record or statement material to a false or fraudulent claim;

(3) Conspire to commit a violation under this subtitle;

(4) Have possession, custody, or control of money or other property used by or on behalf of the State under a State health plan or a State health program and knowingly deliver or cause to be delivered to the State less than all of that money or other property;

(5) (i) Be authorized to make or deliver a receipt or other document certifying receipt of money or other property used or to be used by the State under a State health plan or a State health program; and (ii) Intending to defraud the State or the Department, make or deliver a receipt or document knowing that the information contained in the receipt or document is not true;

(6) Knowingly buy or receive as a pledge of an obligation or debt publicly owned property from an officer, employee, or agent of a State health plan or a State health program who lawfully may not sell or pledge the property;

(7) Knowingly make, use, or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or other property to the State;

(8) Knowingly conceal, or knowingly and improperly avoid or decrease, an obligation to pay or transmit money or other property to the State; or

(9) Knowingly make any other false or fraudulent claim against a State health plan or a State health program.

447. Defendants violated the Maryland False Claims Act, and knowingly caused false claims to be made, used and presented to the State of Maryland by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

448. The State of Maryland, by and through the Maryland Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

449. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Maryland in connection with Defendants' conduct. Compliance with applicable Maryland statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Maryland.

450. Had the State of Maryland known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by

healthcare providers and third party payers in connection with that conduct.

451. As a result of Defendants' violations of the Maryland False Claims Act, the State of Maryland has been damaged in an amount far in excess of millions of dollars exclusive of interest.

452. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Maryland False Claims Act on behalf of himself and the State of Maryland.

453. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Maryland in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF MARYLAND:

(1) Three times the amount of actual damages which the State of Maryland has sustained as a result of Defendants' conduct;

(2) A civil penalty of not more than $10,000 for each false claim which Defendants caused to be presented to the State of Maryland;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Maryland False Claims Act and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XV
(Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.601 *et seq.*)

454. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

455. This is a *qui tam* action brought by Relator on behalf of the State of Michigan to recover treble damages and civil penalties under Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.603, which provides in pertinent part:

> (1) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact in an application for medicaid benefits.
>
> (2) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact for use in determining rights to a medicaid benefit. . . .

456. Defendants violated Michigan law and knowingly caused false claims to be made, used and presented to the State of Michigan by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

457. The State of Michigan, by and through the Michigan Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

458. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Michigan in connection with Defendants' conduct. Compliance with applicable Michigan statutes was also a condition of payment of claims submitted to the State of Michigan.

459. Had the State of Michigan known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

460. As a result of Defendants' violations of the Medicaid False Claims Act, the State of Michigan has been damaged in an amount far in excess of millions of dollars exclusive of interest.

461. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Medicaid False Claims Act on behalf of himself and the State of Michigan.

462. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Michigan in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF MICHIGAN:

(1) Three times the amount of actual damages which the State of Michigan has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Michigan;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to the Medicaid False Claims Act and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XVI
(Minnesota False Claims Act, M.S.A. § 15C.01 *et seq.*)

463. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

464. This is a *qui tam* action brought by Relator on behalf of the State of Minnesota to recover treble damages and civil penalties under the Minnesota False Claims Act, M.S.A. § 15C.01 *et seq.*

(1) Minnesota False Claims Act, M.S.A. § 15C.02, provides for liability for any person who: knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(2) knowingly makes or uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(3) knowingly conspires to commit a violation of clause (1), (2), (4), (5), (6), or (7);

(4) has possession, custody, or control of property or money used, or to be used, by the state or a political subdivision and knowingly delivers or causes to be delivered less than all of that money or property;

(5) is authorized to make or deliver a document certifying receipt for money or property used, or to be used, by the state or a political subdivision and, intending to defraud the state or a political subdivision, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(6) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the state or a political subdivision who lawfully may not sell or pledge the property; or

> (7) knowingly makes or uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state or a political subdivision, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state or a political subdivision.

465. Defendants violated the Minnesota False Claims Act and knowingly caused false claims to be made, used and presented to the State of Minnesota by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

466. The State of Minnesota, by and through the Minnesota Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

467. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Minnesota in connection with Defendants' conduct. Compliance with applicable Minnesota statutes was also a condition of payment of claims submitted to the State of Minnesota.

468. Had the State of Minnesota known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

469. As a result of Defendants' violations of the Minnesota False Claims Act, the State of Minnesota has been damaged in an amount far in excess of millions of dollars exclusive of

interest.

470. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Minnesota False Claims Act on behalf of himself and the State of Minnesota.

471. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Minnesota in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF MINNESOTA:

(1) Three times the amount of actual damages which the State of Minnesota has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Minnesota;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Minnesota False Claims Act and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XVII
(Montana False Claims Act, MCA § 17-8-401 *et seq.*)

472. Relator realleges and incorporates by reference the prior paragraphs as though fully

set forth herein.

473. This is a *qui tam* action brought by Relator on behalf of the State of Montana to recover treble damages and civil penalties under the Montana False Claims Act, MCA § 17-8-401 *et seq.*

474. Montana's False Claims Act, MCA § 17-8-403, provides for liability for any person who:

> (a) knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;
>
> (b) knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim;
>
> (c) conspires to commit a violation of this subsection (1);
>
> (d) has possession, custody, or control of public property or money used or to be used by the governmental entity and knowingly delivers or causes to be delivered less than all of the property or money;
>
> (e) is authorized to make or deliver a document certifying receipt of property used or to be used by the governmental entity and, with the intent to defraud the governmental entity or to willfully conceal the property, makes or delivers a receipt without completely knowing that the information on the receipt is true;
>
> (f) knowingly buys or receives as a pledge of an obligation or debt public property of the governmental entity from any person who may not lawfully sell or pledge the property;
>
> (g) knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to a governmental entity or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to a governmental entity; or
>
> (h) as a beneficiary of an inadvertent submission of a false or fraudulent claim to the governmental entity, subsequently discovers the falsity of the claim or that the claim is fraudulent and fails to disclose the false or fraudulent claim to the governmental entity within a reasonable time after discovery of the false or fraudulent claim.

475. Defendants violated the Montana False Claims Act and knowingly caused false claims to be made, used and presented to the State of Montana by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

476. The State of Montana, by and through the Montana Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

477. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Montana in connection with Defendants' conduct. Compliance with applicable Montana statutes was also a condition of payment of claims submitted to the State of Montana.

478. Had the State of Montana known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

479. As a result of Defendants' violations of the Montana False Claims Act, the State of Montana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

480. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Montana False Claims Act on behalf of himself and the State of Montana.

481. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Montana in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF MONTANA:

(1) Three times the amount of actual damages which the State of Montana has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Montana;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Montana False Claims Act and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XVIII

(Nevada False Claims Act, Nev. Rev. Stat. Ann. § 357.010 *et seq.*)

482. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

483. This is a *qui tam* action brought by Relator on behalf of the State of Nevada to recover treble damages and civil penalties under the Nevada False Claims Act, Nev. Rev. Stat. Ann. § 357.010 *et seq.*

484. N.R.S. § 357.040(1) provides liability for any person who:

(a) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval.

(b) Knowingly makes or uses, or causes to be made or used, a false record or statement that is material to a false or fraudulent claim.

(c) Has possession, custody or control of public property or money used or to be used by the State or a political subdivision and knowingly delivers or causes to be delivered to the State or a political subdivision less money or property than the amount of which the person has possession, custody or control.

(d) Is authorized to prepare or deliver a document that certifies receipt of money or property used or to be used by the State or a political subdivision and knowingly prepares or delivers such a document without knowing that the information on the document is true.

(e) Knowingly buys, or receives as a pledge or security for an obligation or debt, public property from a person who is not authorized to sell or pledge the property.

(f) Knowingly makes or uses, or causes to be made or used, a false record or statement that is material to an obligation to pay or transmit money or property to the State or a political subdivision.

(g) Knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State or a political subdivision.

(h) Is a beneficiary of an inadvertent submission of a false claim and, after discovering the falsity of the claim, fails to disclose the falsity to the State or political subdivision within a reasonable time.

(i) Conspires to commit any of the acts set forth in this subsection.

485. Defendants violated N.R.S. § 357.040(1) and knowingly false claims to be made, used and presented to the State of Nevada by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

486. The State of Nevada, by and through the Nevada Medicaid program and other state

healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

487. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Nevada in connection with Defendants' conduct. Compliance with applicable Nevada statutes was also a condition of payment of claims submitted to the State of Nevada.

488. Had the State of Nevada known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

489. As a result of Defendants' violations of N.R.S. § 357.040(1), the State of Nevada has been damaged in an amount far in excess of millions of dollars exclusive of interest.

490. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.R.S. § 357.080(1) on behalf of himself and the State of Nevada.

491. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Nevada in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the STATE OF NEVADA:

(1) Three times the amount of actual damages which the State of Nevada has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Nevada, except that this upper limit on liability is subject to an automatic adjustment in accordance with the CPIAA;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.R. S. § 357.040 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XIX
(New Jersey False Claims Act, N.J.S.A. § 2A:32C-1 *et seq.*)

492. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

493. This is a *qui tam* action brought by Relator on behalf of the State of New Jersey to recover treble damages and civil penalties under the New Jersey False Claims Act, N.J.S.A. § 2A:32C-1 *et seq.*

494. N.J.S.A. § 2A:32C-3, provides for liability for any person who:

(a) Knowingly presents or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;

(b) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State;

(c) Conspires to defraud the State by getting a false or fraudulent claim allowed or paid by the State;

(d) Has possession, custody, or control of public property or money used or to be used by the State and knowingly delivers or causes to be delivered less property than the amount for which the person receives a certificate or receipt;

(e) Is authorized to make or deliver a document certifying receipt of property used or to be used by the State and, intending to defraud the entity, makes or delivers a receipt without completely knowing that the information on the receipt is true;

(f) Knowingly buys, or receives as a pledge of an obligation or debt, public property from any person who lawfully may not sell or pledge the property; or

(g) Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

495. Defendants violated the New Jersey False Claims Act and knowingly caused false claims to be made, used and presented to the State of New Jersey by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

496. The State of New Jersey, by and through the New Jersey Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

497. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of New Jersey in connection with Defendants' conduct. Compliance with applicable New Jersey statutes was also a condition of payment of claims submitted to the State of New Jersey.

498. Had the State of New Jersey known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

499. As a result of Defendants' violations of the New Jersey False Claims Act, the State of New Jersey has been damaged in an amount far in excess of millions of dollars exclusive of interest.

500. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the New Jersey False Claims Act on behalf of himself and the State of New Jersey.

501. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Jersey in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF NEW JERSEY:

(1) Three times the amount of actual damages which the State of New Jersey has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than and not more than the civil penalty allowed under the federal False Claims Act for each false claim which Defendants caused to be presented to the State of New Jersey;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to New Jersey False Claims Act and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XX
(New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.*; New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. § 44-9-1 *et seq.*)

502. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

503. This is a *qui tam* action brought by Relator on behalf of the State of New Mexico to recover treble damages and civil penalties under the New Mexico Fraud Against Taxpayers Act, which provides in pertinent part:

A person shall not:

(1) knowingly present, or cause to be presented, to an employee, officer or agent of the state or a political subdivision or to a contractor, grantee, or other recipient of state funds or political subdivision funds a false or fraudulent claim for payment or approval;

(2) knowingly make or use, or cause to be made or used, a false, misleading or fraudulent record or statement to obtain or support the approval of or the payment on a false or fraudulent claim; or

(3) conspire to defraud the state or a political subdivision by obtaining approval or payment on a false or fraudulent claim . . . .

N.M. Stat. Ann. § 44-9-3(A)(1)-(3).

504. Defendants violated N.M. Stat. Ann. §§ 27-14-1 *et seq.* and N.M. Stat. Ann. § 44-9-1 *et seq.* and knowingly caused false claims to be made, used and presented to the State of New Mexico by its deliberate and systematic violation of federal and state laws and by virtue of the fact

that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

505. The State of New Mexico, by and through the New Mexico Medicaid program and other state healthcare programs, and unaware of Defendant' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

506. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of New Mexico in connection with Defendants' conduct. Compliance with applicable New Mexico statutes was also a condition of payment of claims submitted to the State of New Mexico.

507. Had the State of New Mexico known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

508. As a result of Defendants' violations of N.M. Stat. Ann. §§ 27-14-1 *et seq.* and N.M. Stat. Ann. § 44-9-1 *et seq.*, the State of New Mexico has been damaged in an amount far in excess of millions of dollars exclusive of interest.

509. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.M. Stat. Ann. §§ 27-14-1 *et seq.* and N.M. Stat. Ann. § 44-9-1 *et seq.,* on behalf of himself and the State of New Mexico.

510. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate

damage to the State of New Mexico in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF NEW MEXICO:

(1) Three times the amount of actual damages which the State of New Mexico has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of New Mexico;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.M. Stat. Ann. §§ 27-14-1 *et seq.* and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XXI
(New York State False Claims Act, N.Y. State Fin. Law § 188 *et seq.*)

511. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

512. This is a *qui tam* action brought by Relator on behalf of the State of New York to recover treble damages and civil penalties under the New York State False Claims Act, N.Y. State Fin. Law § 188, which imposes liability on any person who:

(a) knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or

statement material to a false or fraudulent claim; or

(c) conspires to commit a violation of paragraph (a), (b) . . . .

513. Defendants violated the New York State False Claims Act, and knowingly caused false claims to be made, used and presented to the State of New York, by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

514. The State of New York, by and through the New York Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

515. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of New York in connection with Defendants' conduct. Compliance with applicable New York statutes was also a condition of payment of claims submitted to the State of New York.

516. Had the State of New York known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

517. As a result of Defendants' violations of the New York State False Claims Act, the State of New York has been damaged in an amount far in excess of millions of dollars exclusive of interest.

518. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the New York State False Claims Act, on behalf of himself and the State of New York.

519. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New York in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF NEW YORK:

(1) Three times the amount of actual damages which the State of New York has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $6,000 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of New York;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to the New York State False Claims Act, and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XXII
(North Carolina False Claims Act, N.C. Gen. Stat. Ann. § 1-605 *et seq.)*

520. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

521. This is a *qui tam* action brought by Relator on behalf of the State of North Carolina to recover treble damages and civil penalties under the North Carolina False Claims Act, N.C. Gen. Stat. Ann. § 1-605 *et seq.*

522. North Carolina's False Claims Act, N.C.G.S.A. § 1-607, provides for liability for any person who:

> (1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval.
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.
>
> (3) Conspires to commit a violation of subdivision (1), (2), (4), (5), (6), or (7) of this section.
>
> (4) Has possession, custody, or control of property or money used or to be used by the State and knowingly delivers or causes to be delivered less than all of that money or property.
>
> (5) Is authorized to make or deliver a document certifying receipt of property used or to be used by the State and, intending to defraud the State, makes or delivers the receipt without completely knowing that the information on the receipt is true.
>
> (6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from any officer or employee of the State who lawfully may not sell or pledge the property.
>
> (7) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State.

523. Defendants violated the North Carolina False Claims Act, and knowingly caused

false claims to be made, used and presented to the State of North Carolina by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

524. The State of North Carolina, by and through the North Carolina Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

525. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of North Carolina in connection with Defendants' conduct. Compliance with applicable North Carolina statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of North Carolina.

526. Had the State of North Carolina known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

527. As a result of Defendants' violations of the North Carolina False Claims Act, the State of North Carolina has been damaged in an amount far in excess of millions of dollars exclusive of interest.

528. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the North Carolina False Claims Act on behalf of himself and the State of North Carolina.

529. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of North Carolina in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF NORTH CAROLINA:

(1) Three times the amount of actual damages which the State of North Carolina has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of North Carolina;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to North Carolina False Claims Act and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XXIII

(Oklahoma Medicaid False Claims Act, 63 Okl. Stat. Ann. Tit. 63, § 5053 *et seq.*)

530. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

531. This is a *qui tam* action brought by Relator on behalf of the State of Oklahoma to recover treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, 63 Okl. Stat. Ann. Tit. 63, § 5053 *et seq.*

532. Oklahoma's Medicaid False Claims Act, 63 Okl. St. Ann. § 5053.1, provides for liability for any person who:

> (1) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (3) Conspires to commit a violation of the Oklahoma Medicaid False Claims Act;
>
> (4) Has possession, custody, or control of property or money used, or to be used, by the state knowingly delivers, or causes to be delivered, less than all of such money or property;
>
> (5) Is authorized to make or deliver a document certifying receipt of property used or to be used by the state and, intending to defraud the state, makes or delivers the receipt without completely knowing that the information on the receipt is true;
>
> (6) Knowingly buys or receives as a pledge of an obligation or debt, public property from an officer or employee of the state who lawfully may not sell or pledge the property; or
>
> (7) Knowingly makes, uses or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state.

533. Defendants violated the Oklahoma Medicaid False Claims Act and knowingly caused false claims to be made, used and presented to the State of Oklahoma by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

534. The State of Oklahoma, by and through the Oklahoma Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by

healthcare providers and third party payers in connection therewith.

535. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Oklahoma in connection with Defendants' conduct. Compliance with applicable Oklahoma statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Oklahoma.

536. Had the State of Oklahoma known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

537. As a result of Defendants' violations of the Oklahoma Medicaid False Claims Act, the State of Oklahoma has been damaged in an amount far in excess of millions of dollars exclusive of interest.

538. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Oklahoma Medicaid False Claims Act on behalf of himself and the State of Oklahoma.

539. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Oklahoma in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF OKLAHOMA:

(1) Three times the amount of actual damages which the State of Oklahoma has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Oklahoma;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Oklahoma Medicaid False Claims Act and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XXIV
(Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.)*

540. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

541. This is a *qui tam* action brought by Relator on behalf of the State of Rhode Island to recover treble damages and civil penalties under the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.*

542. Rhode Island's False Claims Act, Gen. Laws 1956, § 9-1.1-3, provides for liability for any person who:

(1) Knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(3) Conspires to commit a violation of subdivisions 9-1.1-3(1), (2), (3), (4),

(5), (6) or (7);

(4) Has possession, custody, or control of property or money used, or to be used, by the state and knowingly delivers, or causes to be delivered, less property than all of that money or property;

(5) Is authorized to make or deliver a document certifying receipt of property used, or to be used, by the state and, intending to defraud the state, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the state, or a member of the guard, who lawfully may not sell or pledge the property; or

(7) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state.

543. Defendants violated the Rhode Island False Claims Act and knowingly caused false claims to be made, used and presented to the State of Rhode Island by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

544. The State of Rhode Island, by and through the Rhode Island Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

545. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Rhode Island in connection with Defendants' conduct. Compliance with applicable Rhode Island statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Rhode Island.

546. Had the State of Rhode Island known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

547. As a result of Defendants' violations of the Rhode Island False Claims Act, the State of Rhode Island has been damaged in an amount far in excess of millions of dollars exclusive of interest.

548. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Rhode Island False Claims Act on behalf of himself and the State of Rhode Island.

549. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Rhode Island in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF RHODE ISLAND:

(1) Three times the amount of actual damages which the State of Rhode Island has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Rhode Island;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Rhode Island False Claims Act and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XXV

(Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*)

550. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

551. This is a *qui tam* action brought by Relator on behalf of the State of Tennessee to recover treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*

552. Section 71-5-182(a)(1) provides liability for any person who:

a. Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval under the medicaid program;

b. Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim under the medicaid program;

c. Conspires to commit a violation of subdivision (a)(1)(A), (a)(1)((B), or (a)(1)((D); or

d. Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money, or property to the state, or knowingly conceals, or knowingly and improperly, avoids, or decreases an obligation to pay or transmit money or property to the state, relative to the medicaid program.

553. Defendants violated Tenn. Code Ann. § 71-5-1 82(a)(1) and knowingly caused false claims to be made, used and presented to the State of Tennessee by the conduct alleged herein and by virtue of the fact that none of the claims submitted in connection with its conduct were even

eligible for reimbursement by the government-funded healthcare programs.

554. The State of Tennessee, by and through the Tennessee Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

555. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Tennessee in connection with Defendants' conduct. Compliance with applicable Tennessee statutes was also a condition of payment of claims submitted to the State of Tennessee.

556. Had the State of Tennessee known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

557. As a result of Defendants' violations of Tenn. Code Ann. § 71-5-182(a)(1), the State of Tennessee has been damaged in an amount far in excess of millions of dollars exclusive of interest.

558. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Tenn. Code Ann. § 71-5-183(a)(1) on behalf of himself and the State of Tennessee.

559. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Tennessee in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF TENNESSEE:

(1) Three times the amount of actual damages which the State of Tennessee has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Tennessee, except that this upper limit on liability is subject to an automatic adjustment in accordance with the CPIAA;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Tenn. Code Ann. § 71-5-183(c) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XXVI
(Texas False Claims Act, V.T.C.A. Hum. Res. Code § 36.001 *et seq.*)

560. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

561. This is a *qui tam* action brought by Relator on behalf of the State of Texas to recover double damages and civil penalties under V.T.C.A. Hum. Res. Code § 36.001 *et seq.*

562. V.T.C.A. Hum. Res. Code § 36.002 provides liability for any person who:

(1) knowingly makes or causes to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is

authorized;

(2) knowingly conceals or fails to disclose information that permits a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized;

(3) knowingly applies for and receives a benefit or payment on behalf of another person under the Medicaid program and converts any part of the benefit or payment to a use other than for the benefit of the person on whose behalf it was received;

(4) knowingly makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:

a. the conditions or operation of a facility in order that the facility may qualify for certification or recertification required by the Medicaid program, including certification or recertification as . . .

b. information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;

(5) except as authorized under the Medicaid program, knowingly pays, charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or product or the continued provision of a service or product if the cost of the service or product is paid for, in whole or in part, under the Medicaid program;

(6) knowingly presents or causes to be presented a claim for payment under the Medicaid program for a product provided or a service rendered by a person who:

a. is not licensed to provide the product or render the service, if a license is required; or

b. is not licensed in the manner claimed;

(7) knowingly makes or causes to be made a claim under the Medicaid program for:

a. a service or product that has not been approved or acquiesced in

by a treating physician or health care practitioner;

b. a service or product that is substantially inadequate or inappropriate when compared to generally recognized standards within the particular discipline or within the health care industry; or

c. a product that has been adulterated, debased, mislabeled, or that is otherwise inappropriate;

(8) makes a claim under the Medicaid program and knowingly fails to indicate the type of license and the identification number of the licensed health care provider who actually provided the service;

(9) conspires to commit a violation of Subdivision (1), (2), (3), (4), (5), (6), (7), (8), (10), (11), (12), or (13);

(10) is a managed care organization that contracts with the commission or other state agency to provide or arrange to provide health care benefits or services to individuals eligible under the Medicaid program and knowingly:

a. fails to provide to an individual a health care benefit or service that the organization is required to provide under the contract;

b. fails to provide to the commission or appropriate state agency information required to be provided by law, commission or agency rule, or contractual provision; or

c. engages in a fraudulent activity in connection with the enrollment of an individual eligible under the Medicaid program in the organization's managed care plan or in connection with marketing the organization's services to an individual eligible under the Medicaid program;

(11) knowingly obstructs an investigation by the attorney general of an alleged unlawful act under this section;

(12) knowingly makes, uses, or causes the making or use of a false record or statement material to an obligation to pay or transmit money or property to this state under the Medicaid program, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to this state under the Medicaid program; or

(13) knowingly engages in conduct that constitutes a violation under

Section 32.039(b).

563. Defendants violated V.T.C.A. Hum. Res. Code § 36.002 and knowingly caused false claims to be made, used and presented to the State of Texas by engaging in the conduct alleged herein and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

564. The State of Texas, by and through the Texas Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

565. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Texas in connection with Defendants' conduct. Compliance with applicable Texas statutes was also a condition of payment of claims submitted to the State of Texas.

566. Had the State of Texas known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

567. As a result of Defendants' violations of V.T.C.A. Hum. Res. Code § 36.002, the State of Texas has been damaged in an amount far in excess of millions of dollars exclusive of interest.

568. Defendant did not, within 30 days after it first obtained information as to such violations, furnish such information to officials of the State responsible for investigating false

claims violations, did not otherwise fully cooperate with any investigation of the violations, and has not otherwise furnished information to the State regarding the claims for reimbursement at issue.

569. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to V.T.C.A. Hum. Res. Code § 36.101 on behalf of himself and the State of Texas.

570. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Texas in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF TEXAS:

(1) Two times the amount of actual damages which the State of Texas has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $11,000 pursuant to V.T.C.A. Hum. Res. Code § 36.025(a)(3) for each false claim which Defendants caused to be presented to the state of Texas, except that this upper limit on liability is subject to an automatic adjustment in accordance with the CPIAA;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to V.T.C.A. Hum. Res. Code § 36.110, and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XXVII
(Vermont False Claims Act, Vt. Stat. Ann. tit. 32, § 630 *et seq.)*

571. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

572. This is a *qui tam* action brought by Relator on behalf of the State of Vermont to recover treble damages and civil penalties under the Vermont False Claims Act, Vt. Stat. Ann. tit. 32, § 630 *et seq.*

573. Vt. Stat. Ann. tit. 32, § 631(a) in pertinent part provides for liability for any person who:

> (1) knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval;
>
> (2) knowingly make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (3) knowingly present, or cause to be presented, a claim that includes items or services resulting from a violation of 13 V.S.A. chapter 21 or section 1128B of the Social Security Act, 42 U.S.C. §§ 1320a-7b;
>
> (4) knowingly present, or cause to be presented, a claim that includes items or services for which the State could not receive payment from the federal government due to the operation of 42 U.S.C. § 1396b(s) because the claim includes designated health services (as defined in 42 U.S.C. § 1395nn(h)(6)) furnished to an individual on the basis of a referral that would result in the denial of payment under 42 U.S.C. chapter 7, subchapter XVIII (the "Medicare program"), due to a violation of 42 U.S.C. § 1395nn;
>
> * * *
>
> (9) knowingly make, use or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State;
>
> (10) knowingly conceal or knowingly and improperly avoid or decrease an obligation to pay or transmit money or property to the State; or

* * *

(12) conspire to commit a violation of this subsection.

574. Defendants furthermore violated the Vt. Stat. Ann. tit. 32, § 630, *et seq.*, and knowingly caused false claims to be made, used and presented to the State of Vermont by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

575. The State of Vermont, by and through the Vermont Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

576. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Vermont in connection with Defendants' conduct. Compliance with applicable Vermont statutes and regulations was also an express condition of payment of claims submitted to the State of Vermont.

577. Had the State of Vermont known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

578. As a result of Defendants' violations of the Vt. Stat. Ann. tit. 32, § 630, *et seq.*, the State of Vermont has been damaged in an amount far in excess of millions of dollars exclusive of interest.

579. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Vt. Stat. Ann. tit. 32, § 630, *et seq.*, on behalf of himself and the State of Vermont.

580. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Vermont in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF VERMONT:

(1) Three times the amount of actual damages which the State of Vermont has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Vermont, except that this upper limit on liability is subject to an automatic adjustment in accordance with the CPIAA;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in investigating and bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to the Vermont False Claims Act, Vt. Stat. Ann. tit. 32, § 630 *et seq.*, and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XXVIII
(Washington Medicaid Fraud Act, Wash. Rev. Code Ann. § 74.66.005 *et seq.*)

581. Relator realleges and incorporates by reference the prior paragraphs as though fully

set forth herein.

582. This is a *qui tam* action brought by Relator on behalf of the State of Washington to recover treble damages and civil penalties under the Washington Medicaid Fraud Act, Wash. Rev. Code Ann. § 74.66.005 *et seq*.

583. RCWA 74.66.020(1) in pertinent part provides for liability for any person who:

> (a) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (b) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or
>
> (c) Conspires to commit one or more of the violations in this subsection (1).

584. Defendants violated the Washington Medicaid Fraud Act, Wash. Rev. Code Ann. § 74.66.005 *et seq*., and knowingly caused false claims to be made, used and presented to the State of Washington by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

585. The State of Washington, by and through the Washington Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

586. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Washington in connection with Defendants' conduct. Compliance with applicable Washington statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Washington.

587. Had the State of Washington known that Defendants were violating the federal and

state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

588. As a result of Defendants' violations of the Washington Medicaid Fraud Act, Wash. Rev. Code Ann. § 74.66.005 *et seq.*, the State of Washington has been damaged in an amount far in excess of millions of dollars exclusive of interest.

589. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Washington Medicaid Fraud Act, Wash. Rev. Code Ann. § 74.66.005 *et seq*. on behalf of himself and the State of Washington.

590. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Washington in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF WASHINGTON:

(1) Three times the amount of actual damages which the State of Washington has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Washington;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Washington Medicaid Fraud Act, Wash. Rev. Code Ann. § 74.66.005 *et seq*. and/or any other applicable provision

of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XXIX

(Massachusetts False Claims Act, Mass. Gen. Laws Ann. Ch. 12 § 5(A) *et seq.*)

591. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

592. This is a *qui tam* action brought by Relator on behalf of the Commonwealth of Massachusetts for treble damages and penalties under Massachusetts False Claims Act, Mass. Gen. Laws Ann. Ch. 12 § 5(A) *et seq.*

593. Mass. Gen. Laws Ann. Ch. 12 § 5B(a) provides liability for any person who:

(1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim; or

(3) conspires to commit a violation of this subsection; or

* * *

(10) is a beneficiary of an inadvertent submission of a false claim to the common wealth or political subdivision thereof, or is a beneficiary of an overpayment from the commonwealth or a political subdivision thereof, and who subsequently discovers the falsity of the claim or the receipt of overpayment, and fails to disclose the false claim or receipt of overpayment to the commonwealth or a political subdivision by the later of:

(i) the date which is 60 days after the date on which the false claim or receipt of overpayment was identified; or

(ii) the date any corresponding cost report is due . . . .

594. Defendants violated Mass. Gen. Laws Ann. Ch. 12 § 5B and knowingly caused

false claims to be made, used and presented to the Commonwealth of Massachusetts by the conduct alleged herein and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

595. The Commonwealth of Massachusetts, by and through the Massachusetts Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

596. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Massachusetts in connection with Defendants' conduct. Compliance with applicable Massachusetts statutes was also a condition of payment of claims submitted to the Commonwealth of Massachusetts.

597. Had the Commonwealth of Massachusetts known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

598. As a result of Defendants' violations of Mass. Gen. Laws Ann. Ch. 12 § 5B, the Commonwealth of Massachusetts has been damaged in an amount far in excess of millions of dollars exclusive of interest.

599. Relator is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Mass. Gen. Laws Ann. Ch. 12 § 5(c)(2) on behalf of himself and the Commonwealth of Massachusetts.

600. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Massachusetts in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the Commonwealth OF MASSACHUSETTS:

(1) Three times the amount of actual damages which the Commonwealth of Massachusetts has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the Commonwealth of Massachusetts, except that this upper limit on liability is subject to an automatic adjustment in accordance with the CPIAA;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Mass. Gen. Laws Ann. Ch. 12, § 5F and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XXX

(Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.*)

601. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

602. This is a *qui tam* action brought by Relator on behalf of the Commonwealth of Virginia for treble damages and penalties under Virginia Fraud Against Taxpayers Act, Va. Code

Ann. § 8.01-216.3(A), which provides liability for any person who:

> (1) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (3) Conspires to commit a violation of subdivision 1, 2, 4, 5, 6, or 7; or
>
> * * *
>
> (7) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Commonwealth or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Commonwealth.

603. Defendants furthermore violated Virginia's Fraud Against Tax Payers Act, § 8.01-216.3(A), and knowingly caused false claims to be made, used and presented to the Commonwealth of Virginia by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

604. The Commonwealth of Virginia, by and through the Virginia Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

605. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the Commonwealth of Virginia in connection with Defendants' conduct. Compliance with applicable Virginia statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the Commonwealth of Virginia.

606. Had the Commonwealth of Virginia known that Defendants were violating the

federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

607. As a result of Defendants' violations of Virginia's Fraud Against Tax Payers Act, §8.01-216.3a, the Commonwealth of Virginia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

608. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Virginia's Fraud Against Tax Payers Act, §8.01-216.3, on behalf of himself and the Commonwealth of Virginia.

609. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Virginia in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the COMMONWEALTH OF VIRGINIA:

(1) Three times the amount of actual damages which the Commonwealth of Virginia has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the Commonwealth of Virginia;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to VA Code Ann. § 32.1-315 and/or

any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XXXI
(District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. § 2-381.02 *et seq.*)

610. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

611. This is a *qui tam* action brought by Relator and the District of Columbia to recover treble damages and civil penalties under the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. § 2-381.02 *et seq.*

612. D.C. Code § 2-381.02(a) provides liability for any person who:

(1) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(3) Has possession, custody, or control of property or money used, or to be used, by the District and knowingly delivers, or causes to be delivered, less than all of that money or property;

(4) Is authorized to make or deliver a document certifying receipt of property used, or to be used, by the District and, intending to defraud the District, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(5) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the District who lawfully may not sell or pledge property;

(6) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the District, or knowingly conceals or knowingly and improperly avoids or

decreases an obligation to pay or transmit money or property to the District;

(7) Conspires to commit a violation of paragraph (1), (2), (3), (4), (5), or (6) of this subsection;

(8) Is a beneficiary of an inadvertent submission of a false or fraudulent claim to the District, subsequently discovers the falsity of the claim, and fails to disclose the false or fraudulent claim to the District; or

Is the beneficiary of an inadvertent payment or overpayment by the District of monies not due and knowingly fails to repay the inadvertent payment or overpayment to the District.

613. Defendants violated D.C. Code § 2-381.02 and knowingly caused false claims to be made, used and presented to the District of Columbia by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its illegal conduct were even eligible for reimbursement by the government-funded healthcare programs.

614. The District of Columbia, by and through the District of Columbia Medicaid program and other District healthcare programs, and unaware of Defendants' illegal conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

615. Compliance with the Anti-Kickback Statute and applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the District of Columbia in connection with Defendants' conduct. Compliance with applicable District of Columbia statutes was also a condition of payment of claims submitted to the District of Columbia.

616. Had the District of Columbia known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by

healthcare providers and third party payers in connection with that conduct.

617. As a result of Defendants' violations of D.C. Code § 2-308.14(a), the District of Columbia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

618. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to D.C. Code § 2-308.15(b) on behalf of himself and the District of Columbia.

619. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the District of Columbia in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the DISTRICT OF COLUMBIA:

(1) Three times the amount of actual damages which the District of Columbia has sustained as a result of Defendants' illegal conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the District of Columbia, except that this upper limit on liability is subject to an automatic adjustment in accordance with the CPIAA;

(3) Pre- and post-judgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to D.C. Code § 2-308.15(f) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

JURY TRIAL DEMANDED

620. Relator demands a jury trial.

DATED: April 17, 2018

Respectfully submitted,

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